



# National Health and Nutrition Examination Survey (NHANES)

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## Taste and Smell Examination Component Manual



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# **1. OVERVIEW OF TASTE AND SMELL COMPONENT**

## **1.1 Background of Taste and Smell Perception**

The vast majority of people with smell and taste disorders have problems with smell, not taste. Smell plays the most important role in appreciating flavors in eating. Common “tastes” such as chocolate, coffee, strawberry, apple, peach, pizza, steak sauce, and chicken actually reflect smell-mediated sensations: odors from chewing food are released and propelled upwards towards the olfactory receptors via the posterior nasal pharynx. Taste buds, located mainly on the tongue surface, palate, and oropharynx, are primarily responsible for mediating sweet, sour, bitter, salty, and metallic sensations. The roles of the taste system include: (1) triggering digestive reflex systems that alter secretions of saliva, stomach acid, and pancreatic juices; (2) enhancing the feelings of pleasure and satiety when eating; and (3) enabling the determination of the quality of sampled foodstuffs and distinguishing nutrients, which usually taste “good” (e.g., sweet) from potential toxins, which usually taste “bad” (e.g., bitter). Although not usually appreciated, taste dysfunction can alter food choices and patterns of consumption, producing weight loss, malnutrition, and in some cases impaired immunity and even death. In someone who is hypertensive or diabetic, taste loss can lead to a dangerous tendency to overcompensate for the loss of a sense of taste by adding additional salt or sugar to the food.

## **1.2 Basic Principles of Taste and Smell**

### **1.2.1 The Sense of Smell**

The sense of smell is mediated by specialized smell receptor cells of the nasal cavity. These smell receptors, unlike the receptors of most sensory systems, are directly exposed to the outside environment, except for a thin protective layer of mucus, making them relatively susceptible to damage from such exogenous agents as viruses, bacteria, pollutants, and airborne toxins. A number of factors influence the function of smell in “normal” individuals. These include age, gender, and smoking habits, among others. Of these three, aging is by far the most important. Medical treatments and the use of medications and drugs have also been shown to profoundly affect the sense of smell.

### 1.2.1.1 Olfactory (Smell) System

The olfactory system is able to recognize a great variety of odors or substances and discriminate subtle differences between chemicals. The primary olfactory receiving center of the brain is the “olfactory bulb.” After processing in the olfactory bulb, physiological signals for smell are delivered directly to the olfactory areas in the brain.

The nasal passages are complex, dynamic channels for breathing and smell detection. The inside of the nasal passages are covered with mucus membranes.<sup>2</sup>

The location of the smell receptors in the nasal passages is shown in Figure 1-1. This illustration shows maps of the nasal lining illustrated with plus (+) signs of the location where biopsy specimens contained olfactory epithelium or fascicles of the olfactory nerve indicate the location of olfactory mucosa smell receptors. The minus (-) signs indicate that no olfactory epithelium or nerve was found.

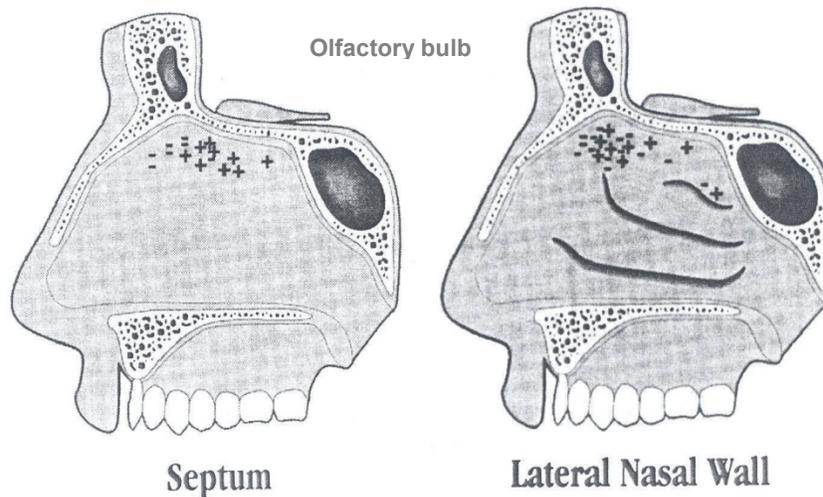


Figure 1-1. Maps of the nasal lining

The numbers and the distribution of smell receptors in the nasal passages are known to vary within and between individuals. Factors such as chemical exposure, bacterial and viral infection, and head trauma may affect the distribution and it has been shown that the olfactory epithelium decreases with age.

## **1.2.2 The Sense of Taste**

Taste or gustation is one of the two main chemical senses. Humans detect taste with taste receptor cells. These are clustered in taste buds which are not visible to the naked eye. Most of them are buried in specialized structures called papillae on specific parts of the tongue. These papillae give the tongue its bumpy appearance. Most of the bumps are filiform papillae but there are other types of papillae. The papillae on the tongue have no taste function. Filiform papillae come in different shapes. In the cat, they are shaped like tiny spoons with sharp edges. They help the cat lap up liquids. The filiform papillae on our tongues do not have these sharp edges. Thus, if we try to lap fluids from a dish, we will find it to be a tiring task. The taste buds themselves are distributed in a line across the roof of the mouth and in papillae distributed in an oval on the surface of the tongue. Normally we have no subjective awareness of this distribution of taste buds.

Taste cells have a limited life span. After a few days they die and are replaced by new cells. This constant renewal allows the taste system to recover from a variety of sources of damage and explains why our taste systems tend to remain robust even into old age.

### **1.2.2.1 Transduction and the Four Basic Tastes**

The first event in the sensation of taste is the contact between a substance to be tasted (the “tastant”) and a site on the microvillus that extends from the taste receptor cell. The signal that is generated by this contact is called a “transduction.” Transduction mechanisms are very different for different tastes. We can divide the transduction mechanisms into two groups: salty and sour acids versus bitter and sweet. Salts and sour acids are made up of charged particles; bitter and sweet stimuli have particular molecular shapes that fit complementary shapes on the microvilli of the taste cells.

There are four “basic tastes” (sweet, salty, bitter, and sour). Sweet is the taste of the sugars that are biologically useful to us (sucrose, fructose, and glucose); the sweet taste of mother’s milk may serve to produce suckling immediately after birth before an infant has had time to learn the consequences of ingesting milk. Salty is the taste of sodium, a mineral that must be available in relatively large quantities to maintain nerve and muscle function; loss of body sodium leads to a swift death. Bitter is the taste of many poisons. Sour is the taste of acid that in high enough concentrations can damage tissue.

When we consider the functions that taste performs, we can see how important that coding is. If taste mixtures behaved as do color mixtures, we would have a problem. For example, pure salt is not often found in nature. The ability to analyze a mixture to detect the presence of salt is critical to survival. Similarly, poisonous plants contain components with a variety of tastes; if bitterness were to synthesize with those other tastes, we could not identify it and thus avoid the poison. The functions of the four tastes are well served by keeping them independent of one another.

Adaptation, a powerful phenomenon in taste also operates to maintain the separation of the four tastes. Perhaps one of the best demonstrations of taste adaptation is our own saliva. For example, if we rinse our mouths with distilled water and then taste a salt solution of the same salt content that saliva has, the solution tastes salty. But normally we are adapted to the same concentration of salt in our saliva so we do not taste it; we only taste saltiness from concentrations above that to which we are adapted.

### **1.2.2.2 Genetic Differences in the Ability to Taste**

Part of the ability to detect bitter tastes is genetically determined. The best example of this is the ability to taste phenylthiocarbamide (PTC) which has been used for many years in taste studies. There is natural variation in the ability to taste PTC in the population – some people cannot taste it, some are average tasters, and some are extremely sensitive to it (“supertasters”). In modern taste testing studies, a chemical relative of PTC that was safer to test, 6-n-propylthiouracil (“PROP” or “PTU”) is used instead of PTC. Taste studies have shown that tasters may be more finicky eaters (they do not like bitter-tasting foods as much as nontasters) and there may be a relationship between taster status, obesity, and health. Also, there is some research that links genetic variation in bitter taste preference to preferences for sweet and fat in foods.

## **1.3 Medical Disorders of the Chemosenses**

Individuals with taste and smell impairments may be at increased risk of health and nutritional problems and also at risk of safety problems from fire and gas explosions. Many factors contribute to taste and smell impairments, such as medications/drugs, radiation therapy, unhealthy habits (cigarette smoking), head trauma, chronic sinusitis and rhinitis, and some toxic environmental exposures.

There is a great need to discover the extent of taste and smell problems, especially for older Americans, and to educate them (and caregivers) about potential hazards and ways to avoid these hazards.

### **1.3.1 Disorders of Smell**

The most common causes of permanent smell loss are upper respiratory infections, head trauma or injury, and chronic rhinosinusitis. Although the data are limited, these causes account for the majority of patients who present to physicians with chemosensory problems. Other less common causes of smell loss include chronic alcoholism, epilepsy, and neurological disorders such as multiple sclerosis, Alzheimer's disease, and Parkinson's disease. There is some literature to suggest that smell testing of persons who may be at risk for Alzheimer's disease may be a predictor of who later will be clinically diagnosed with that disease.

Exposure to a number of toxic chemicals can induce smell loss. Olfactory loss can occur as a result of exposure to air pollution and to chemical exposures in the workplace. In addition to directly damaging the smell receptors, some chemicals may produce damage indirectly by inducing upper respiratory inflammatory responses or infections that, in turn, cause damage. The best scientifically documented examples of smell loss due to chemical exposures in humans are for acrylates, methacrylates, and cadmium. It should be noted that tobacco smoke is known to have a high amount of cadmium.

### **1.3.2 Disorders of Taste**

The most debilitating taste disorders are those in which there is a persistent, chronic bad taste in the mouth, such as a bitter, salty, or "metallic" taste. The causes of this fall into two broad categories: (1) cases where an abnormal substance actually gains access to the mouth, and (2) "taste phantoms" that occur when there is nothing in the mouth. Taste phantoms originate in the brain itself. Tastants can enter the mouth in a number of ways (e.g., from metals in oral appliances, from infected discharge from the teeth or gums, from medications that enter the saliva, or from postnasal drip). Among offending medicines are lipid reducing agents, antibiotics, blood pressure medications, anxiety drugs, and antidepressants.

Taste phantoms can result from tumors putting pressure on taste structures in the brain, but more commonly result from localized damage to the taste system. Inputs from the different nerves for taste normally interact with one another at the level of the brain and nerve damage can alter this process to produce taste phantoms. Fortunately, many of these problems resolve on their own over time due to the ability of the taste nerves to regenerate after damage.

#### **1.4 Importance of Taste and Smell Data**

The current NHANES study is designed to provide normative reference data for the ability to smell and taste in the U.S. adult population. The senses of taste and smell monitor the intake into the body of all the body's nutrients. The sense of smell, more than any other, determines the flavor and palatability of foods and beverages. A primary aim of this NHANES study is to correlate natural physiologic variations in the ability to smell and taste with NHANES nutritional and obesity data. Also, our sense of smell is important as it provides us early warning of dangers from toxic fumes, smoke, leaking natural gas, and spoiled food. Data will also be collected in this important area. Further, NHANES plans to collect questionnaire data on the prevalence of clinical smell and taste disorders in the U.S., as there is currently a lack of reliable data on this.

The NHANES Taste and Smell examination component is co-sponsored by the National Institute on Deafness and Other Communication Disorders (NIDCD). The NHANES taste and smell examination protocol consists of smell testing with the 8-item Modified Pocket Smell Test; and taste testing for salt and bitter tastes. A household interview questionnaire will also be administered to assess personal health history data for taste and smell disorders.

The prevalence of smell and taste impairments in the U.S. is unknown. A recent publication based on a community study estimated that approximately 14 million older adults in the U.S. may suffer from impairment of the sense of smell.<sup>1</sup> Less is known about the prevalence of taste impairments. Most people are unaware that flavor perception is largely mediated by retronasal odorant stimulation of smell receptors while chewing and swallowing and that altered flavor perception is often due to smell, not taste, deficits. This confusion about the relative importance of taste- vs. smell-mediated effects limits the utility of studying taste and smell disorders by self-reported questionnaire data, and emphasizes the need to collect health examination data on taste and smell.

There is only one known population-based study in the United States that has measured olfactory function and reported on the prevalence of olfactory impairment.<sup>1</sup> This was a community study performed in conjunction with the Epidemiology of Hearing Loss Study (EHLS), a study of sensory loss and aging in Wisconsin which had a sample size of 3,407 participants. There were two earlier prevalence studies of olfactory impairment in U.S. adults, the National Geographic Society Smell Survey,<sup>2</sup> and the 1994 National Health Interview Survey (NHIS) – Disability Supplement.<sup>3</sup> There were, however, major drawbacks with both these studies. The National Geographic Society study was not population-based and the smell examination tests were self-administered. The NHIS-Disability Supplement study was population-based, but ascertained chronic (3+ months) smell problems based on an interviewee’s self-reported responses during a home interview. Proxy responses, usually from spouses, were used if the partner was not present during the interview. Both studies reported a much lower prevalence of smell impairments (about 2% for all adults and 5% for subjects aged 75+ years) compared to the examination-based Wisconsin community study which found a smell impairment prevalence of 24.5 percent among adults 53+ years of age, and a prevalence of almost 30 percent among those aged 70–79 years. There are no nationally representative studies from other countries; however, community-based studies have been conducted in Europe. For example, in a recent German community study of adults between the ages 25-75 years, the examination-based prevalence of smell and taste impairment was 16.2 percent and 17.5 percent, respectively.<sup>4</sup> In total, the preliminary data from community-based examination studies suggests that smell and taste disorders may represent a substantial public health burden for the U.S. adult population. These findings highlight the need to obtain accurate U.S. prevalence estimates for these disorders.

#### **1.4.1 Public Health Goals of the NHANES Study**

In the healthy normal population, genetic variation in taste and smell may explain some of the differences in food preferences and part of the risk of diet-related diseases such as obesity, hypertension, diabetes, and other medical problems. Also age-related changes in flavor perception, specific health conditions, and environmental exposures may contribute to changes in food palatability and nutritional intake, which may affect health. Individuals with taste and smell impairments are often unaware of their deficits. This is demonstrated in most studies where the prevalence of taste and smell impairments as measured by health examination testing exceeds the prevalence of self-reported taste and smell problems. Therefore, many clinical taste and smell problems in the general population are likely to be undiagnosed. Obtaining high quality, examination-based measures of taste and smell function is useful for prevalence estimation of taste and smell impairments.

Impaired odor and flavor perception, as identified by smell examination testing, may dull the flavor of foods and beverages. It is known that metabolic rate, energy intake, and macronutrient intake decrease with age, and food selection can become increasingly important in maintaining energy balance. Also, there is evidence that individuals with smell loss tend to gain weight rather than lose it, i.e., such individuals may derive less reward value from food and require more food to be satisfied. NHANES, via its nationally representative nutritional data collection, its health examination data, and genetic sample database, is an ideal venue to study such issues.

This survey protocol focuses on establishing the range of salt and bitter taste perception in the general population. Taste ability and taste preferences are also a major public health priority. For example, in the 2010 Institute of Medicine (IOM) Report, “Strategies to Reduce Sodium Intake in the United States,” it is recommended that Federal agencies should ensure and enhance monitoring and surveillance relative to sodium intake measurement, salt taste, and sodium content of foods.<sup>5</sup> This recommendation is specifically to address the current burden of dietary salt intake as a major contributor to hypertension and cardiovascular disease mortality. The currently proposed examination protocol helps to address these needs, and complements the current NHANES projects to implement population-based sodium intake biomonitoring in its 2011+ survey.

In addition to the above need to define the range of physiological variation in smell and taste ability, there is an important public health need to determine the current population prevalence of overt taste and smell disorders. This is an estimate of the numbers of U.S. adults who may potentially benefit from medical treatment. Previous smaller scale studies indicate that a person’s awareness of a taste or smell disorder is poor: the proportion of persons with demonstrable taste or smell impairment on objective examination far exceeds the prevalence of self-reported taste and smell disorders. This is a situation similar to hypertension, where there is a large population of undiagnosed cases. However, there is also a general public health issue in that medical providers in the U.S. do not routinely test for the presence of taste or smell disorders. This is due to a lack of awareness of the extent of the problem by the medical profession. This is despite the fact that disorders of taste and smell may pose significant safety or health risks to patients, for example, the inability to smell smoke, natural gas, or spoiled food products, or the effects of impairments of smell and taste on nutrition among older Americans. The currently proposed protocol will provide data to help increase the awareness of these disorders among both the general public and in the medical community. The questionnaire will also establish baseline data from which to track increases or decreases in the prevalence of these disorders in support of Healthy People 2020 objectives.

In recognition of their general public health importance, the Federal Interagency Workgroup for Healthy People 2020 has added taste and smell disorder-related goals to its surveillance monitoring agenda.<sup>6</sup> This is in recognition of the disabling health consequences of the loss of the normal ability to smell and taste. Specific Healthy People 2020 goals include: (1) increase the proportion of adults with chemosensory (smell or taste) disorders who have seen a health care provider about their disorder in the past 12 months; (2) increase the proportion of adults who have tried recommended methods of treating their smell or taste disorders in the past 12 months to improve their condition; and (3) reduce the proportion of adults with chemosensory (smell or taste) disorders who as a result have experienced a negative impact on their general health status, work, and other daily activities, or quality of life in the past 12 months.<sup>7</sup> The NHANES household interview questionnaire will support monitoring of all three goals in a 2011+ NHANES survey.

## **1.5 Overview of the Taste and Smell Examination**

The NHANES Smell and Taste Examination has six parts.

### **1. Pre-examination Screening Questions**

Before beginning the Taste and Smell examination, exclusion questions will be asked: participants who are pregnant or nursing a child will be excluded from the entire Taste and Smell exam; participants with a history of skin rash or allergy due to quinine will not do quinine taste testing, but will complete all other parts of the Taste and Smell exam. Following this, a short series of questions will be asked to screen the SP for certain conditions that they may currently have such as a head cold or sinus problem that may influence the interpretation of the exam results. These are not exclusion questions. This additional supportive data will help distinguish the prevalence of temporary vs. permanent loss of taste or smell.

### **2. Explanation of the Smell and Taste Exam Item Rating Scale**

The participant will be asked to rate the strength of each smell or taste item on a uniform rating scale (the Generalized Labeled Magnitude Scale or gLMS). They will be instructed in the use of the scale and have an opportunity for practice by rating two lights presented on an LED screen. Then they rate the brightness of a standard series of three lights presented to them (a dim, a moderate, and a bright light). If they rate these three lights in the correct order on the gLMS scale, they will proceed with the Taste exam. If they do not rate their order correctly, they will not do Taste testing (which depends on the use of the gLMS scale) but will proceed to Smell testing.

### 3. Taste Examination Test Section

- Each participant will be asked to taste and rate the intensity of up to three solutions.
  - 0.32 M NaCl (salt);
  - 1 mM quinine (flavor component of tonic water and bitter lemon); and
  - 1 M NaCl (salt).

The quinine solution and the 1 M NaCl solution will be painted across the tip of the tongue and also sampled by sipping and swishing in the mouth. Both concentrations of the salt solution (.32 M and 1 M NaCL) and the quinine will be sipped, swished around, and spit out in order to be perceived with the whole mouth.

SPs will rinse with water in between each tastant. For each of the three test tastants, SPs will be asked to rate the intensity of the taste on the gLMS scale and to identify the taste.

### 4. The Odor Identification Test Section

The Modified Pocket Smell Test will be used, this test is an 8-item “scratch and sniff” test contained in two cards. The NHANES protocol will ask the participant to identify the smell out of four given choices presented for each item. This smell testing includes a test item for smoke and natural gas, which are important from a safety point of view.

### 5. The Salt Replicate Test Section

Following the smell testing, a single replicate whole mouth salt test will be administered as a quality control check on the participant's scale ratings. This will be randomized between the .32 M and the 1 M NaCl solutions.

### 6. Health Technologists Rating of Participant Understanding of the Testing

Finally, the health technologist will rate the participants' level of understanding of the smell and taste testing protocol.

To coordinate with the Smell and Taste Examination, an NHANES household interview questionnaire will collect data on the prevalence of self-reported taste and smell problems, a previous history of medical treatment for taste and smell disorders, and data on medical conditions that increase the likelihood of smell and taste disorders.

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## 2. EQUIPMENT AND SUPPLIES

The Taste and Smell test will be conducted in trailer 3 of the mobile examination center (MEC). The room will be equipped with features designed to facilitate accurate and efficient examinations. This chapter describes the taste and smell equipment and supplies and explains the procedures for the setup, operation, and pack-up of the taste and smell component.

### 2.1 Equipment

- Sensory Perception light source  
This is a light source with six calibrated luminance values used to give the SP practice using the gLMS.
- Hanna Portable Lux Meter  
Hand-held light meter for verifying the luminance values of the sensory perception light box.
- Porto-Dent II Suction Machine  
This is a portable dental grade vacuum device to manage the expectorate from the tastants sampled and the water rinses taken between sampling tastants.
- Spare suction canister assembly  
Spare steel suction canister to switch out between sessions if necessary (max. capacity = 2 liters).
- Gooseneck microphone stand with slip-on clip  
Holds the suction tubing and dry oral cup; the metal gooseneck can be adjusted to the SP's comfort.
- Dry oral evacuation funnel (cuspidor)  
Plastic funnel attached to the suction tubing into which a paper liner is placed for the SP to expectorate.
- High-volume evacuation valve  
Connector between the funnel cup and the vacuum hose; it controls the level of suction via a valve that opens and closes.
- Low-volume vacuum line plug  
Plug to close the second vacuum line when not in use, and for protecting the vacuum lines during travel.

Figures 2-1 to 2-11 show photos of the taste and smell equipment.

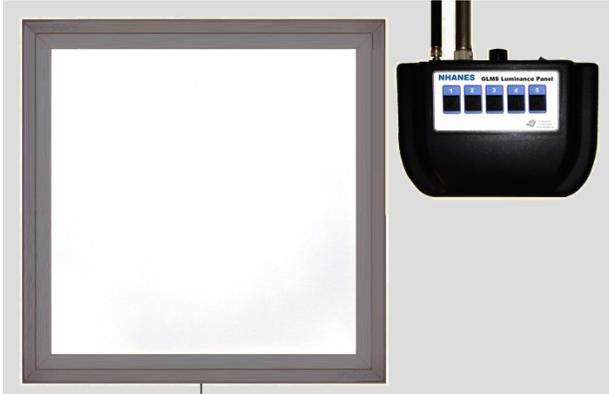


Figure 2-1. Sensory Perception Light Box



Figure 2-2. Portable Lux Meter



Figure 2-3. Porto-Dent II Suction Machine (front view)



Figure 2-4. Porto-Dent II Suction Machine (back view)



Figure 2-5. Porto-Dent II Suction Machine – cabinet view



Figure 2-6. Porto-Dent II Suction Machine – cabinet view with canister

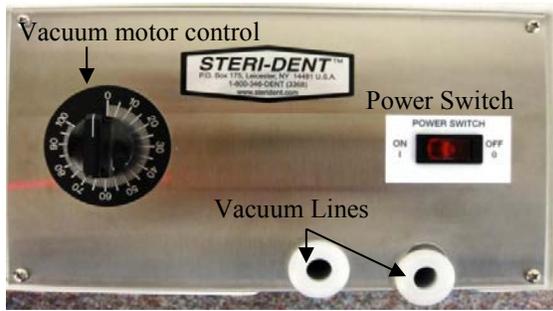


Figure 2-7. Porto-Dent II Suction Machine – front control panel

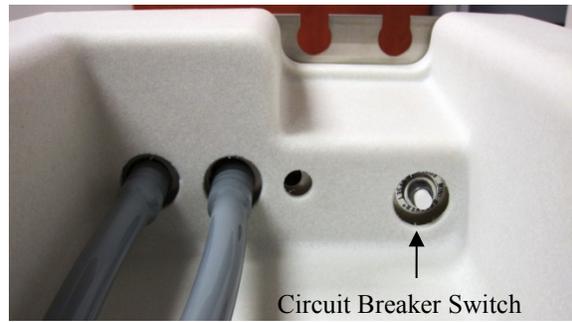


Figure 2-8. Porto-Dent II Suction Machine – circuit breaker reset switch



Figure 2-9. Spare Canister assembly



Figure 2-10. Gooseneck microphone stand with slip-on clip



Figure 2-11. Dry oral evacuation funnel



Figure 2-12. High-volume evacuation valve



Figure 2-13. Low-volume vacuum line plug

## 2.2

### Supplies

The following supplies will be available in the MEC for the taste and smell examination.

- Modified Pocket Smell Test            The modified pocket smell test is an 8-Odor, forced-choice screening test.
- Stylus                                    Plastic stylus used to scratch the odor test patches on the smell test.
- Tastant solutions                    These are a series of three tastant solutions prepackaged in small 10 ml vials. The tastants will be 1.0 mM solution of quinine, 0.32 M and 1 M standard salt solutions (NaCl).
- Replicate tastant solutions        These are two replicate tastant solutions prepackaged in small 10 ml vials. The tastants will be 0.32 M and 1 M standard salt solutions (NaCl).
- Wooden tip applicator                The health tech will use the wooden tip applicator for the tip-of-the-tongue test.
- Laminated Generalized Labeled Magnitude Scale (gLMS)        SPs will use this scale to rate the strength of each tastant.
- Set of reading glasses                Reading glasses of different magnifications available in the room for people who may have forgotten theirs or do not have them.
- Dry erase marker pens                Pens are used to mark the laminated gLMS.
- Dry oral funnel paper liners         Single use paper liner that fits into the oral funnel cup.
- Dry-back dental bibs-blue            Plastic-backed barrier is to be placed around the base of the microphone stand to catch incidental splashing.
- Distilled water                        Used for SPs to rinse their mouths before and between tastants.
- Saline solution                        This 0.32 M NaCl solution is for SPs to rinse their mouths if needed.
- Mouthwash (Scope)                 Used for SPs to quench their mouths if an unpleasant taste remains in their mouths at the end of the exam.
- Plastic cups                            Used to pour the water.
- Tissue                                    Tissues are provided as a general supply for use as needed.
- Sugar-free jelly beans                Provided for SPs to help get rid of the tastant's taste, if needed. These are only used in PM and evening exam sessions.

- VacuKleen E2 Enzymatic Evacuation System Cleaner      Protease enzyme vacuum line cleaner supplied in premeasured powder packets; removes protein-based deposits.
- 2-liter plastic container      The container is large enough to hold enough water to reconstitute Vacukleen E2 Enzymatic Evacuation Cleaner.
- Sani-Cloth<sup>®</sup> germicidal wipes      Used to clean the oral funnel cup between SPs and to clean the inside of the canister cabinet.
- Examination gloves      To be used when administering the taste portion of the component and when cleaning the dry oral cup and emptying suction canister.
- Disposable facial shields      For use when cleaning and emptying the suction canister.
- Formula 409<sup>®</sup> cleaner      Solution for cleaning outside and inside of suction machine and microphone stand.
- Soft cleansing brush      Provided for cleaning the inside of oral evacuation funnel and the high-volume evacuation valve.

Figures 2-14 to 2-17 show photos of the taste and smell component supplies.

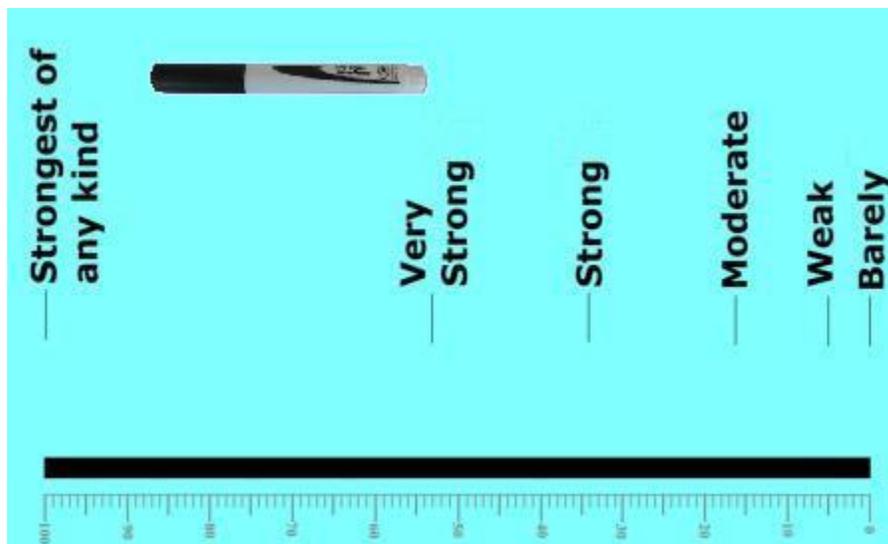


Figure 2-14. gLMS and dry erase marker

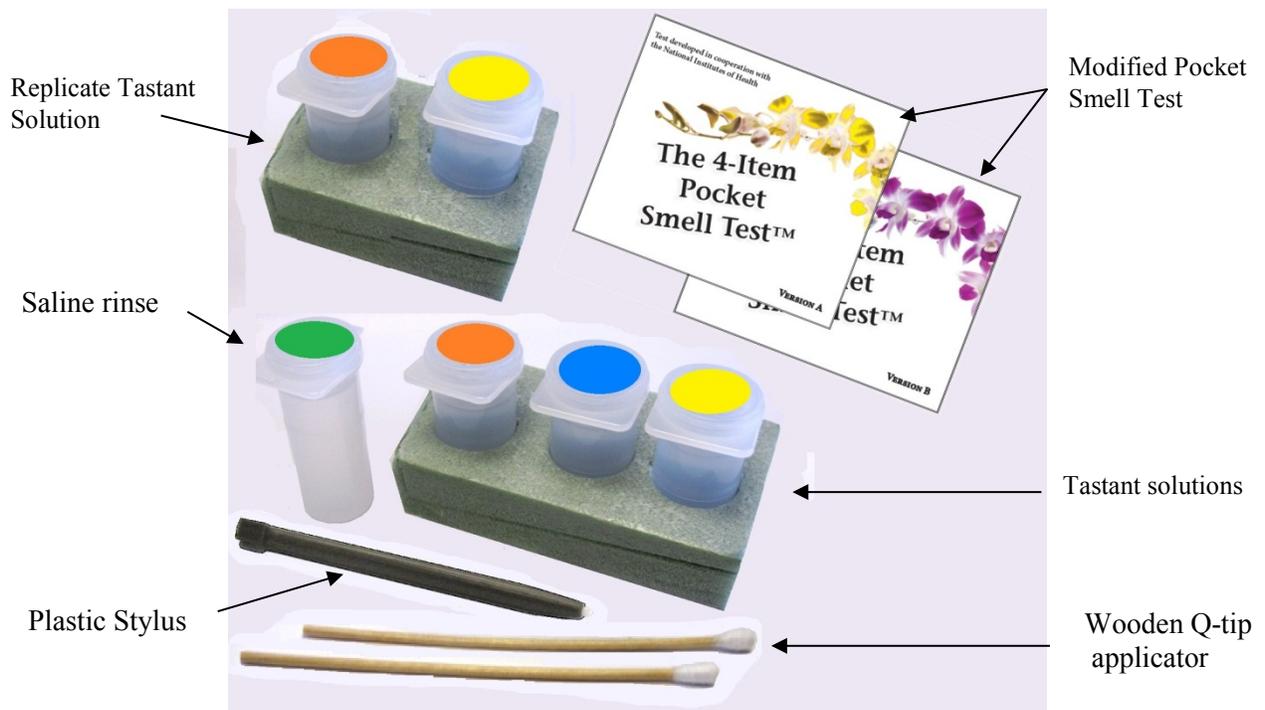


Figure 2-15. Selected supplies for the taste and smell examination (1)



Figure 2-16. Selected supplies for the taste and smell examination (2)



Vacukleen E2 Enzymatic Evacuation System Cleaner

Figure 2-17. Selected supplies for the taste and smell examination (3)

## 2.3 Equipment Care and Maintenance

Follow the procedures below to ensure that the taste and smell equipment functions properly and remains hygienic throughout the stand.

### 2.3.1 Start of Stand and Start of Session

- Clean the surface of the Porto-Dent and microphone stand with Formula 409.
- Obtain one suction canister and lid, and attach to the vacuum line hoses inside the unit. Inspect the inside of the cabinet holding the suction canister, making sure the surfaces are clean. Clean only with Formula 409.

**NOTE:** Do not use bleach. Bleach corrodes metal and damages the stainless steel canister as well as the vacuum system over time.

- Test the functioning of the vacuum by turning on the unit and turning the dial to 50. Detect the suction level with a gloved finger at the end of the HVE valve to confirm that the unit is functioning. Turn off the unit when finished.

- Inspect the oral funnel cup for any debris or soil and clean with Formula 409 and rinse with water. Let air dry.
- Using a Sani-Cloth germicidal wipe, clean the outside of the oral funnel cup, and then the inside of the cup.

**NOTE:** The Formula 409 cleaner can be used to remove dirt, but it is not suitable for use as a disinfectant.

### 2.3.2 Equipment Care and Maintenance between SP's

- Wearing gloves, discard the blue dental bib and oral funnel cup paper liner. It is not necessary to touch the paper liner; simply dump it directly into the trash.

**NOTE:** This is not a biohazardous item, so the regular trash may be used.

- Using a Sani-Cloth wipe, clean the outside of the oral funnel cup, and then the inside of the cup. Let air dry. If the base of the cup appears soiled, take the cup to the sink and wash with water and Formula 409.
- Using another Sani-Cloth wipe, clean around the base of the microphone stand, as well as the gooseneck.
- Inspect the Porto-Dent cabinet and control panel and clean if necessary with Formula 409.
- Check the level of fluid in the suction canister after four SPs have gone through the exam in one session.
- When the oral funnel cup is dry, replace the paper liner.
- Roll the suction unit back against the wall.
- Notify the coordinator that the room is ready.

Depending on the amount of water the SP uses to rinse between tastants, and the number of SPs who get this exam in a given session, it might be necessary to empty the contents of the canister during the session. The procedures for emptying and cleaning the canister are described in Section 2.2.3 below. The canister can hold up to 2 liters of fluid.

### 2.3.3 End of Session

Checking the appointment schedule for the number of taste and smell-eligible SP's, as well as keeping track of the number of taste and smell exams completed, will assist the health technologist to predict whether the canister will need to be emptied at the end of the session. The health technologist assigned to the taste and smell components for that week will be responsible for emptying and cleaning the canister at the end of the session. It is important to note that the canister has a bolt on the bottom, and it does not rest directly on a surface when it is removed. For that reason, it is important to place the canister onto a container that stabilizes it when it is full to avoid tipping and spillage.

- Personal protective equipment should be worn in case of splashing:
  - Safety goggles and face mask OR facial shield;
  - Disposable lab jacket; and
  - Gloves.
- Before emptying the canister, make sure all liquid is out of the vacuum line tubing: turn on the power, set the dial to at least 50, and extend the tubing vertically until it is fully extended for at least 10 seconds with the vacuum running. This will better ensure that all remaining fluid in the line is pulled into the suction canister. Turn dial back to zero, and turn off unit. The unit does not need to be unplugged to empty the canister.
- Have the second vacuum canister ready to install.
- Disconnect the vacuum line from the top of the suction canister, and place a dental bib below the outlet to catch any dripping.
- Remove the full suction canister. Place it in the carrying container.
- Place the empty suction canister in the cabinet, and securely connect the vacuum tube connector to the lid of the suction canister. If any dripping occurred, clean the cabinet with Formula 409.
- Take the canister to the sink, remove the canister from the carrying container, and rest it in the sink. Remove the lid and empty contents. Rinse the canister lid and canister with warm water. Add a small amount of Dawn dishwashing detergent and warm water to make a soapy emulsion, and use the soft cleansing brush supplied.
- Rinse the canister and lid of all soapy residue and dry with a paper towel.
- Rinse the brush and store in its receptacle under the sink.

- Remove the safety goggles and mask, or the facial shield. Both the safety goggles and facial shield are reusable. If you did not splash any liquids on the disposable lab jacket, it may be reused.

#### 2.3.4 Daily

The calibration of the light source will be verified daily using the Hanna Portable Lux Meter. Exposure measurements will be taken at the surface of the LCD panel (P-reading) and at a standard distance. The standard distance will be comparable to the distance between the SP and the LCD panel (SP reading). Refer to Appendix D for detailed instructions on how to verify the calibration of the light source.

The vacuum line must be cleaned **daily**, at the end of the second session of the day. The enzyme cleaner, VacuKleen E2, is specially manufactured for vacuum line cleaning and removes protein deposits and also deodorizes the system. To use the enzyme cleaner follow these steps:

- Perform end of session maintenance if the canister was used during that session. (There may be sessions when a taste and smell exam was not done.) Make sure you are wearing personal protective gear as specified above.
- Mix one packet of VacuKleen E2 with 1 quart of warm tap water in the plastic jug. VacuKleen E2 is a protease enzyme specifically designed to break down saliva, blood, and tissue.
- Slowly run all of the VacuKleen solution through the vacuum line in use through the oral funnel cup at the lowest possible setting, i.e., 10. The vacuum lines will drain by gravity, so it is not necessary to turn on the vacuum. The cup must be higher than the machine to drain effectively.
- Empty and rinse the canister in the sink.
- Inspect the HVE valve for residue. If dirty, take the valve to the sink to clean. Clean with a small amount of Dawn dishwashing liquid and the small brush supplied for the HVE valve.

#### 2.4 Equipment Malfunctions

All equipment malfunctions or repair needs must be reported promptly to the chief technologist, MEC manager, and home office component specialist. If the issue is computer-related and

cannot be resolved by the chief technologist and/or MEC manager, please contact the home office ISIS support staff.

Equipment issues should be documented in the Unusual Field Occurrence (UFO) system and Equipment Tracking System (ETS) as appropriate (refer to the *UFO Utility Manual* and *ETS User Guide* for details). The component specialist will contact the equipment manufacturer for assistance.

A complete set of backup taste and smell equipment is kept at the home office for training and ISIS testing purposes.

#### **2.4.1 Troubleshooting the Porto-Dent II Suction Machine**

If the suction machine is not working, the following troubleshooting steps should be taken:

- Make sure the unit power switch is on;
- Check the AC connections, and tighten if necessary;
- Open the door and inspect the suction canister connections, and tighten if necessary; and
- Observe the circuit breaker button to determine if it needs to be reset.

#### **2.5 Setup Procedures**

The following procedures describe how to setup the taste and smell equipment and supplies at the start of a stand.

##### **2.5.1 Porto-Dent II**

The suction machine is self-contained and uses a standard AC electrical outlet. See Figures 2-18 to 2-22 below. The only removable piece of the unit is the suction canister assembly. Two vacuum lines rest in holders on the top front panel of the machine; these vacuum lines are permanently affixed to the unit and are not intended for removal. The unit measures 13” x 16” x 26,” weighs 35

pounds, and is fitted with polyethylene carpet casters. The cabinet is constructed of impact-resistant polyethylene plastic. The power source is located in the back where the vacuum motor and canister is accessed for maintenance. The Porto-Dent II motor is sealed and does not require routine maintenance. The motor has an overload circuit breaker reset button in the front of the machine, on the right underside of the metal control panel adjacent to the vacuum lines.

- Open the rear door and remove all bubble wrap that is holding the suction canister securely in place.
- Inspect both of the canisters and lids for dents or damage.
- Check that all hoses within the cabinet are connected to the vacuum line connector (Figure 2-16).
- Remove canister lid and inspect the overflow floater mechanism. The three floater balls should move freely (Figure 2-17).
- Apply lid to canister, making sure to align the black circles (Figure 2-18).
- Mount the canister on the base of the vacuum housing base.
- Attach the connector from the vacuum hoses securely to the top of the canister lid, making certain that the hoses are not twisted or kinked or stretched too tightly.
- Close the door.
- Connect the unit to an AC electrical outlet.
- Attach the HVE valve to the left vacuum line. The HVE valve has a lever on the side that also controls the level of suction. The up position closes the valve; the lower position opens the valve (Figure 2-20).
- Turn switch to ON position, and adjust motor control to test suction. The motor is controlled by a variable speed dial on the left side of the top panel. To increase suction, turn the dial clockwise; to decrease suction, turn the dial counterclockwise. See below for optimal suction instructions.
- Disinfect the dry oral funnel cup with a Sani-Cloth wipe, and connect the cup to the HVE valve.
- Place the gooseneck microphone clip stand on the top of the Porto-Dent, and attach the left vacuum hose to the microphone clip.

**NOTE:** The suction canister and lid are constructed of stainless steel and have a maximum collection capacity of 2 liters of fluid. The underside of the lid has a rubber gasket and simply rests on top of the canister to create the vacuum seal.



Figure 2-18. Vacuum line connector



Figure 2-19. Overflow shut-off mechanism



Figure 2-20. Canister lid alignment indicator markings



Figure 2-21. HVE with lever in the open position "Down"

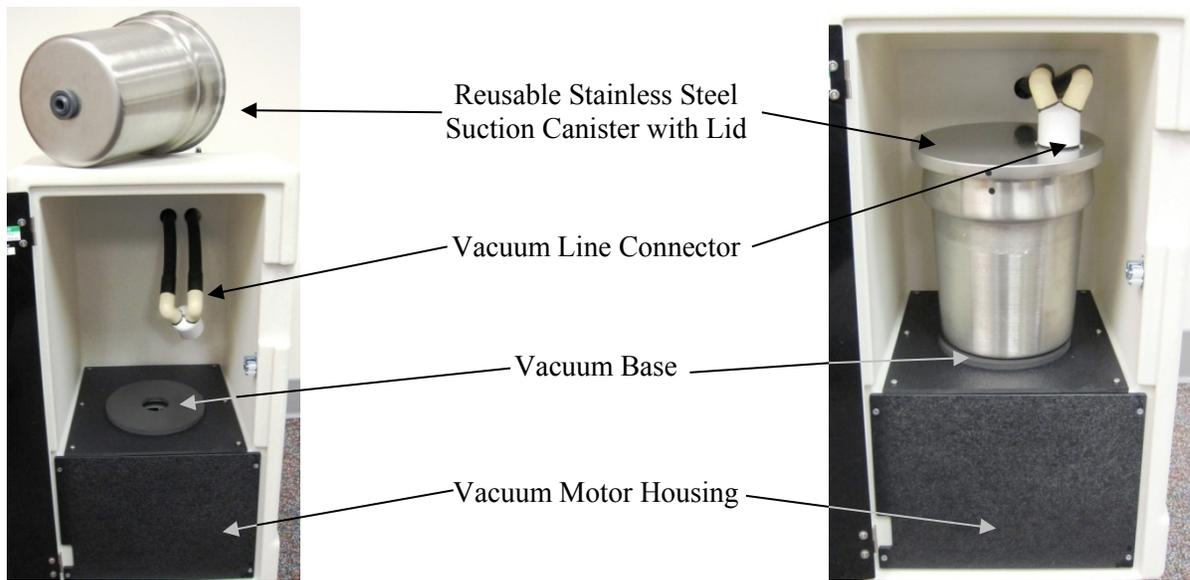


Figure 2-22. Motor and canister assembly inside cabinet

## 2.5.2 Supplies

- Ensure that the following supplies are accessible:
  - Modified Pocket Smell Test (2 cards);
  - Tastant solutions;
  - Replicate Tastant solutions
  - Wooden tip applicators;
  - .32 M Saline solution for rinsing the mouth;
  - Laminated Generalized Labeled Magnitude Scale;
  - Dry erase marker pens;
  - Dry oral funnel paper liners; and
  - Dry-back dental bibs-blue.
- Remove the bungee cord and designated soft padding from the computer monitor and store this in the taste and smell storage container.

- Ensure that the following additional supplies are available:
  - Distilled water;
  - Plastic cups;
  - Tissue;
  - Sugar-free jelly beans;
  - VacuKleen E2 Enzymatic Evacuation System Cleaner;
  - 2-liter plastic container;
  - Sani-Cloth germicidal wipes;
  - Latex gloves;
  - Disposable facial shields;
  - Formula 409 cleaner; and
  - Soft cleansing brush.

## **2.6 Teardown Procedure**

At the end of the stand, follow the procedures described below to pack up the taste and smell equipment.

### **2.6.1 Porto-Dent II**

- Perform end of session maintenance if the canister was used during that session. (There may be sessions when a taste and smell exam was not done.)
- Make sure you are wearing personal protective gear as specified above.
- Mix two packets of VacuKleen E2 with 2 quarts of warm tap water in the plastic jug.
- Slowly run 1 quart through the vacuum line in use through the oral funnel cup at the lowest possible setting, i.e., 10, and the remainder of the solution through the vacuum line not in use.
- Insert vacuum line plugs into the ends of both vacuum lines.

- Remove and inspect the HVE valve for residue, and clean with the small brush supplied for the HVE valve. Place a clean and dried HVE valve into a plastic zip closable bag.
- Empty, rinse, and dry the canister in the lab sink, and return the canister to the taste and smell room.
- Clean gooseneck stand with Sani-Wipe cloth and pack in bin along with the spare suction canister and lid, the funnel cup, and HVE valve. These three items are packed together in a dedicated bin. Place bubble wrap securely around each item.
- Secure the suction canister inside the Porto-Dent II cabinet with bubble wrap until you are sure that the canister is held firmly in place and you are still able to close the cabinet door. For added assurance that the door remains closed, place a piece of masking tape over the door connection.
- Unplug the unit from the AC source.
- Wrap the Porto-Dent II cabinet with padding material and secure it, with a bungee cord, to the designated wall hooks.

## **2.6.2 Supplies**

- Pack the exam supplies in the storage container and
- Discard any trash in the room.

### **3. EXAMINATION PROTOCOL**

#### **3.1 Eligibility Criteria**

The taste and smell exams will be conducted on SPs 40 years and older. There are a few exclusion criteria for the test. SPs with a history of quinine allergy will be excluded from quinine testing but not from any other part of the taste and smell protocol. Pregnant and lactating SPs will be excluded from the entire taste and smell examination component.

#### **3.2 Pre-Examination Procedures**

##### **3.2.1 Pre-Examination Preparation**

Prepare the room for the examination before the SP enters the room. Confirm that all supplies needed for the exam are available and accessible: the Modified Pocket Smell Test cards, stylus, wooden tip applicators, gloves, tissues, tastant solutions, and water. Place the wooden tip applicator into the solutions to be used for the tongue tip taste (blue and orange vials) to saturate them with the tastant solutions before they are used. The taste and smell exam does not require a formal, standard script. However, the examiner will provide a brief introduction to the examination using the following talking points provided (Appendix B):

- Two tests—Taste and smell; and
- Before we begin I will ask you a few questions.
- After your exams today, we will give you a report of the results of your taste and smell tests.

Open the Chemosenses Exam component in ISIS and log onto the system. Wand the SP's identification bracelet.

##### **3.2.2 Pre-Exam Questions**

Before beginning the taste and smell exams, the SP will be asked a short series of questions to screen him or her for exclusion criteria and then additional questions are asked to identify any

conditions he or she may currently have, such as a head cold or sinus problem, that may alter or influence the interpretation of the exam results at the time it is performed. The questions are as follows:

1. Have you ever had a skin rash or allergy caused by quinine?

[HT Help: Quinine is the bitter taste in tonic. Quinine is also used to treat malaria infections (brand name=Lariam).]

[HT Instructions: Code “No” if the SP has never used tonic water.]

2. Are you currently pregnant or breastfeeding a baby?
3. Today, do you have any of the following problems with your nose? Mark all that apply.
  - Sneeze frequently;
  - Green, yellow, or brown mucus discharge;
  - Completely blocked-up nose;
  - Sinus pain; or
  - A head cold or runny nose from the flu.
4. Is your/SP’s nose blocked-up on both sides, or on just one side?

If the SP answers “Yes,” “Don’t Know,” or “Refused” to question 1, he or she will be excluded from quinine taste testing but not from any other part of the taste and smell protocol. If the SP answers “Yes,” “Don’t Know,” or “Refused” to questions 2, she or he will be excluded from the entire exam.

**(INTERVIEWER INSTRUCTION:** Blocked up nose is when you can’t breathe air in and out of the nose. Sinus pain is pain, pressure of fullness in the area of the face behind the cheeks or forehead.)

### 3.2.3 Taste Test

This section of the exam evaluates the SP’s ability to taste two different types of tastants (salty and bitter). Salty and bitter tastes will be tasted using three taste test solutions that come in 10 ml containers (two different salt tastant concentrations and one bitter tastant). Data will be collected on the ability to taste, or not to taste, each test substance, and on the relative magnitude of the taste sensation using the General Labeled Magnitude Scale (gLMS) (see Figure 3-1). The specific tastes selected have been shown to correlate with nutritional and flavor preferences, as well as with health-related risk factors.

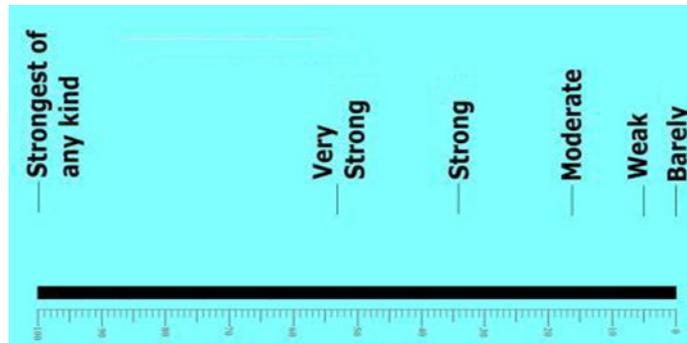


Figure 3-1. General Labeled Magnitude Scale (gLMS)

The taste test does not require a formal, standard script. However, the examiner will provide a brief introduction to the examination using the following talking points provided (Appendix B):

- Purpose – Measure how strongly you taste some common tastes.
- I'll have you taste up to six samples based on how you answered my questions.
  - The first tastes are put on the tip of your tongue, and
  - For the others you swish the taste in your mouth without swallowing.
- Rate how strong the taste is.
- Identify the taste.

Before the taste exam begins, introduce the gLMS, which will be used to rate the strength of brightness of lights and the specific concentrations of tastants during the exam. The gLMS is used because of its advantages for rating the intensity of sensations such as taste. It can be used to rate the intensity of any sensation, such as the brightness of light or the loudness of a sound. The gLMS is a psychometric scale with a total of 100 units presented as a vertical line graph, which has the spaced adjective/adverb labels “barely,” “weak,” “moderate,” “strong,” “very strong,” and “strongest of any kind” spaced at 1, 5, 16, 34, 53 and 100 units, respectively.

The participant will use the gLMS brightness ratings of a series of five lights to guide them in making the ratings of intensity (strength) of the tastes. The gLMS scale is first introduced to the participant with general instructions and then the participant rates the strength or brightness of two lights as practice in using the gLMS. These two “practice” lights give the SP practical experience in using the gLMS scale. Then, the SP will be asked to rate the strength (brightness) of three additional lights (one dim, one moderate, and one bright light) that will serve as standards for comparing the intensity of tastes across the participants. If the SP’s rating of brightness of these three lights are in the correct order they

will proceed with taste testing. If the gLMS ratings are not in the correct order, it will be assumed that the participant does not understand the use of the gLMS scale and he or she will be excluded from the taste testing but not the smell testing. Please remember to show the SP all the lights from the Sensory Perception light source for at least 5 seconds.

The word labels on the gLMS are guides for helping the SP start to make a more exact rating. The procedure for using the gLMS is for the examinee to first pick the word label that is closest to the intensity rating for what he or she experiences, then to determine whether the actual rating is higher or lower than the initial label that was chosen. Next he or she chooses a rating point located between the initially chosen word label and the next adjacent (higher or lower) word label. For example, an examinee picks the initial label “Strong” and then determines that the actual intensity rating is less than “Strong” but more than “Moderate.” He or she would then choose a point between the labels “Strong” and “Moderate” that most accurately reflects the intensity of the taste experienced. In general, the participant should not choose the labels themselves as their ratings, although this will sometimes happen. If the SP chooses a rating close to the word labels, the application will display a warning message. Please remember that the number markings on the MEC version of the gLMS are not a part of the gLMS. The number indicators are only for your use, and the participants should not use the number line to make the intensity ratings.

For the practice lights, begin with the medium-low light (marked as 1); and ask the SP to mark his or her rating for strength of this light on the gLMS. After the SP has rated the medium-low light, show the medium-high light (marked as 2), and ask: “*Would you say that this light is brighter or is it less bright than the previous light?*” Next, ask the SP to make a rating for the medium-high light as before. During the “practice lights,” the SP may require some active coaching to learn how to use the gLMS. You can reshow the SP the medium-low and medium-high lights during the rating of these two sensations to help the SP understand the gLMS.

Once the two practice light ratings are completed, have the SP mark on the gLMS his or her rating of strength (brightness) for the three additional lights (the light standards)—(1) a medium-intensity light (marked as 3); (2) a low-intensity light (marked as 4); and (3) a high-intensity light (marked as 5). Present each light stimulus without telling the participants that they will be rating a strong light or a dim light. When presenting these three lights, please do not give the SP any cues that might bias his or her rating (i.e., do not coach the SP), but do encourage the SP to use the full range of the scale and not just the gLMS labels. You may redisplay a light sensation if the SP wishes to see it again, but please show it before the SP has made his or her brightness rating. As mentioned, participants who fail to correctly rank

the brightness of these three lights (i.e.,  $5 > 3 > 4$ ) will be excluded from taste testing as not understanding the gLMS, but allowed to continue with the smell testing.

For rating the strength of the taste samples (liquids), ask the SP to mark the gLMS with a dry erase marker and rate the **maximum strength** he or she experiences. Probe in a neutral fashion, to verify that the rating is for how strong the tastant is experienced and not how much the SP likes or dislikes the tastant or how surprised he or she is by the taste. When explaining the procedure to the SP, use the phrase, “Please rate the strength of the taste, and make the rating compared to where you have indicated the rating of brightness of the lights.” Do not use the term “intensity” because of potential literacy issues. Throughout the taste test, additional dialogue with or prompting of the SP may be required when: (1) the taste ratings are too high (e.g., too close to their strongest sensation of any kind); (2) the ratings are consistently the gLMS word labels; or (3) the ratings do not change. The maximum strength of the taste sample usually develops right away, so most often the SP’s gLMS rating can be recorded and you can go on to the next test tastant. Occasionally the maximum strength can develop more slowly.

SPs will be asked to taste up to three taste solutions (two salty and one that usually tastes bitter). The first two (1 mM quinine and 1 M NaCl) are painted across the tip of the tongue and then separately sipped and sampled with the whole mouth. The third solution (0.32 M NaCl) is only sipped and perceived with the whole mouth. Instruct the SP to swish each liquid (solution) for a maximum of 3 seconds during the whole mouth taste testing before rating their maximum strength. The SP then spits the liquid out and rinses his or her mouth out with water. When at least 30 seconds have elapsed and the SP reports that there is no residual taste in the mouth, then proceed to test the next taste solution. The taste solutions are not intended for consumption. However, it is not likely to be harmful if a taste solution is accidentally swallowed.

### **3.2.4 The Tongue Tip Taste Test**

The test will start with the tip-of-the-tongue solutions —1 mM quinine and 1 M salt (NaCl). Before each taste solution, please confirm with the SP that there is no lingering taste from the previous solution. The tongue tip taste test does not require a formal, standard script. However, the examiner will provide a brief introduction to the examination using the following talking points provided (Appendix B):

- Apply taste samples across the tip of your tongue (show picture);
- Rate how strong the taste is before you put your tongue back into your mouth;

- Tell me what the taste is; and
- Rinse before we start and after each test.

Position the suction system near the SP, adjust the cup for comfort, or ask him or her to hold the cup. Make sure the SP knows where the cup of water is for mouth rinses. Turn on the evacuator unit, making sure that the suction level is at 20-30 on the variable speed dial. Put a paper towel on the SP's lap to take care of any spills. Provide the cup of water to the SP and ask him/her to rinse their mouth.

Put on gloves and precede with the taste solutions in the order following the color scheme on the ISIS screen. To test the tongue tip properly, fully saturate the cotton-tipped applicator and glide **smoothly** across the surface of the tongue without any resistance or pushing against the surface of the tongue. An unsaturated applicator and excessive touch/tactile stimulation can be uncomfortable for the SP and can distort the taste intensity ratings. Ask the SP to open his or her mouth and extend and relax the tongue as in Figure 3-2. If it is more comfortable, for tongue tip taste testing, the SP may close the lips around the base of the tongue as long as the tongue tip is sticking out. Gently apply the taste with the applicator in one slow continuous motion from the left side of the tongue, across the tip and finishing on the right side of the tongue (Figure 3-2).

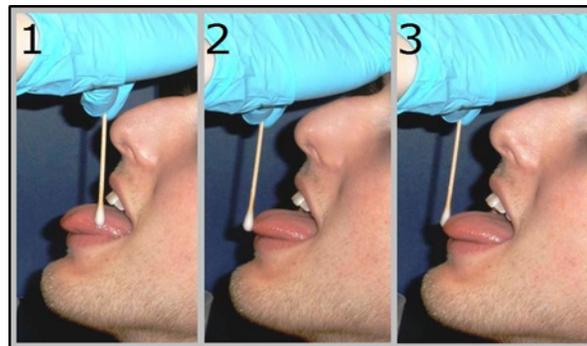


Figure 3-2. The tongue tip taste test

The SP should keep the tongue extended out until the maximum taste strength is reached. Ask the SP to rate the strength of the taste by marking the laminated gLMS and record the rating in ISIS. Taste intensity ratings are usually lower when a taste is sampled on the tip of the tongue compared to being sampled in the whole mouth. This is because there are more taste receptors in the whole mouth than on the tip of the tongue. Therefore, if the SP should accidentally put the tongue back into the mouth before giving the intensity rating, please remind him or her to rate the strength of taste liquid when the tongue was extended, and before he or she put the tongue back in the mouth. If the SP says that he or she does not remember the maximum strength on the tongue tip or the rating does not seem reasonable, ask

the SP to rinse their mouth, wait until no lingering taste is present, and reapply the same taste sample again.

Next, ask the SP to identify what he or she tasted (salty, sour, bitter, no taste, or something else) and record their response in ISIS. Finally, if the SP marks the strength of the tastes close to the top of the scale (“strongest sensation of any kind”) one of the light standards (3, 4, 5,) please query the SP about his or her rating. For example, if the SP rates a taste near the top, then ask if this is similar to the “strongest sensation of any kind”; if it was close to the medium-intensity light, please ask the SP if the strength of the taste was close to the brightness of that light and between, for example, “moderate” and “strong.” Dialogue or coach the SP periodically on the use of the gLMS to help make the intensity ratings of the tastes accurate.

If the SP rates a taste on the tongue-tip as more than 6 (more than weak), but describes the taste as “no taste,” the application will display a warning message.

### 3.2.5 Whole Mouth Taste Test

Next is the whole mouth portion of the taste test. The SP will be given up to three tastants to sip. These taste solutions are color-coded and are administered in one of the two following sequences which will be assigned by ISIS on a random basis:

- 1 M NaCl (orange), 1 mM quinine (blue) and 0.32 M NaCl (yellow); and
- 0.32 M NaCl (yellow), 1 mM quinine (blue) and 1 M NaCl (orange).

Participants answering “Yes,” “Refused,” or “Don’t Know” to the question that asks about a history of quinine-related allergy will be excluded from quinine taste testing.

The whole mouth taste test does not require a formal, standard script. However, the examiner will provide a brief introduction to the examination using the following talking points provided (Appendix B):

- Take all of this solution into your mouth but **DON’T SWALLOW**.
- Gently swish it around for about 3 seconds.
- Spit it out.

- Rate how strong the taste is.
- Tell us what the taste is.
- Rinse after each test with water.
- If you get a taste that is too strong or unpleasant I will give you a rinse to stop the taste.

Following the color scheme on the ISIS screen, give the first solution to the SP. Ask him or her to sip all of the solution from the vial and gently move the solution around in his or her mouth. The SP should not gargle the solution. To make sure that a complete and accurate amount is administered, always check to see if the taste vial is empty after the SP sips it. The SP should move the solution around in his or her mouth for about 3 seconds and then expectorate it into the suction system. Ensure that the suction system dial is between 20- and 30 before the SP spits into it. Have the SP rate the strength of the taste on the gLMS when the taste is strongest. Immediately after, ask what he or she tasted (salty, sour, bitter, no taste, or something else) and enter the data into the ISIS application. The taste samples are not intended for consumption and should be spit out after “tasting” them. Reiterate to the SP that nothing we ask them to “taste” is expected to be harmful. However, if the substance is accidentally swallowed there is not likely to be any harm. In the case that the SP accidentally swallows the solution, they can still give a rating and do not need to start over.

The maximum intensity of a sampled taste usually develops right away. Nevertheless, as long as the taste is increasing for the SP, ask him or her to keep the solution in the mouth until the taste has reached a maximum. Make sure the SP rinses his or her mouth with water between each tastant and formally verify that there is no taste left from the previous solution before going on to administer the next tastant. Make sure at least 30 seconds have elapsed before proceeding with the next solutions. At the end of the test, ask if he or she would like a mouthwash to help get rid of any remaining taste from the solution. Thank the SP for his or her time and effort.

During the taste testing, if the SP misidentifies a tastant (for example, identifies a salt sample as a bitter taste), cross-check to see that the color label for the tastant that was sampled was the correct one. Also, if an SP gives all uniformly high gLMS ratings or uniformly low ones use the gLMS practice ratings to confirm that he or she was using the gLMS properly.

During the exam, or at the end of it, SPs may ask how well they are doing (i.e., the number of correct answers they have made). Alternatively, they may inquire whether they have a taste (or smell) loss or impairment. Assure them there are no “right” or “wrong” answers. Instead, we are measuring the

variability between people and will later correlate these measures to determine if there are factors, which are associated with different taste intensities or sensitivity to certain taste qualities. Tell participants that they will receive a Report of Findings. If any SP is worried that he or she may have (recently) lost the ability to smell or taste, refer him or her to the MEC physician for evaluation and referral.

### **3.2.6 Modified Pocket Smell Test (M-PST)**

The M-PST is an 8-item self-administered “scratch and sniff” test contained in two 4-item Pocket Smell Tests which will be used in parallel. The test odorants are embedded in microcapsules positioned on scent strips at the bottom and top of each page of the test cards. The stimuli to be smelled are released by scratching the strips with a plastic stylus tip. When performing the odor testing identification, the windows must be closed and any fans in the room turned off. The air conditioning can stay on. Also, there should be no other things in the room that would give off a strong odor such as coffee, food, or flowers, and the examiners should not wear strong perfume or cologne.

The smell test does not require a formal, standard script. However, the examiner will provide a brief introduction to the examination using the following talking points provided (Appendix B):

- Purpose – To see how well you can identify some common smells
- Two cards:
  - Each card has 4 smells;
  - Each smell has 4 choices;
  - Look at the four choices while I read them to you; and
  - Tell me which choice is what you smelled.
- If not sure, pick the closest; and
- If no smell, guess.

Open the first card and show the SP the different scent strips. Explain that you will scratch the brown rectangle left to right in a “z” pattern to properly release the test odor. The Modified Pocket Smell Test should be folded one page at a time as the health techs (HTs) proceed with the test. This is done so that SPs only smell one scent of the booklet at a time, and not previously scratched odors as well. After scratching the scent strip, ask the SP to hold the card under his or her nose and sniffs the odor. The SP should be encouraged to sniff the label immediately after it has been scratched to ensure that the odor

has not significantly dissipated. Ask the SP to identify the scent after reading all answer choices from the ISIS screen, and record the SP's answer on the application.

In order for the test to be valid, you must read all the answer choices even if the SP selects one right away. This is especially important in situations where the correct response might be the first choice. If the odor the SP smells is not represented by one of the four choices provided, the SP needs to choose the answer closest to his or her experience. If the SP smells nothing, he or she must guess the best answer.

The M-PST is designed as a forced-choice test, so it is essential that SPs choose one of the four possible responses even if they smell nothing at all. The overall test score can't be calculated unless all eight items are completed. It is known that people with loss of smell may have some remaining ability to smell even if they are not aware of it. This is the reason for prompting them to guess an answer even if they believe they smell nothing. The M-PST is scored by the overall number of items that are correctly identified so there must be an answer for each test scent for the test to be valid.

Once the SP has completed one scent, go immediately to the next scent, and so on, until all eight odorants are completed. There is no need to pause or wait between scents. In some cases, the SPs may request HTs to re-scratch an odor strip. In most cases, it is unnecessary and does not help with identification. The odorants are as follows:

<b>M-PST Items</b>
Chocolate
Strawberry
Smoke
Leather
Soap
Grape
Onion
Natural Gas

To ensure that both the ISIS screen and the booklet are on the correct odorant, the application screen will follow the same order as the cards. Once the SP has completed the card, retrieve it and discard it appropriately.

### 3.2.7 Whole Mouth Solution Replicate Taste Test

Next is the replicate whole mouth solution portion of the taste test. The SP will be given one of the two salt tastants to sip. This tastant will be randomized between the 1 M NaCl (orange) and the 0.32 M NaCl (yellow). The purpose of this test is to see how close this replicate salt test gLMS rating is to the gLMS rating that the SP gave for this same concentration of salt during the main taste testing session.

The whole mouth replicate taste test does not require a formal, standard script. However, the examiner will provide a brief introduction to the examination using the following talking points provided (Appendix B):

- Take all of this solution into your mouth but **DON'T SWALLOW**.
- Gently swish it around for about 3 seconds.
- Spit it out.
- Rate how strong the taste is.
- Tell us what the taste is.
- Rinse after the test with water.
- If you get a taste that is too strong or unpleasant I will give you a rinse to stop the taste.

Following the color scheme on the ISIS screen, give the solution to the SP. Ask him or her to sip all of the solution from the vial and gently move the solution around in his or her mouth. The SP should not gargle the solution in their throat. To make sure that a complete and accurate dose of the tastant is administered for each test, always check to see if the test vial is empty after the SP sips it. The SP should move the solution around in his or her mouth for about 3 seconds and then expectorate it into the suction system. Ensure that the suction system dial is between 20- and 30 before the SP spits into it. Have the SP rate the strength of the taste using the gLMS when the taste is strongest. Immediately after, ask what he or she tasted (salty, sour, bitter, no taste, or something else) and enter the data into the ISIS application. The taste sample is not intended for consumption and should be spit out after “tasting.” Reiterate to the SP that nothing we ask them to “taste” is expected to be harmful. However, if the substance is accidentally swallowed there is not likely to be any harm. In the case that the SP accidentally swallows the solution, he or she can still give a rating without needing to redo the solution.

The maximum strength of a sampled taste usually develops right away. Nevertheless, as long as the taste is increasing for the SP, ask him or her to keep the solution in the mouth until the taste has reached a maximum. Make sure the SP rinses his or her mouth with water after the taste.

During the replicate taste testing, if the SP misidentifies a taste sample (for example, identifies a salt sample as a bitter taste), cross-check to see that the color label for the taste solution that was sampled was the correct one. Please do not coach the SP during the testing of the replicate salt sample. Have the SP rate the replicate salt sample completely on their own. This portion of the taste exam is designed to see how close this replicate salt test gLMS rating is to the original gLMS rating that the SP gave for the same salt concentration during the previous testing. If an SP gives all uniformly high gLMS ratings or uniformly low ones do not use the gLMS practice ratings to confirm the rating.

Only at the end of the taste test, ask the SP if he or she would like a mouthwash to help get rid of any remaining taste from the solution. Thank the SP for his or her time and effort.

### **3.2.8 Participant Evaluation**

This section is to provide information to help determine if the SP had any problems with the entire exam. Rate the SP overall understanding of the entire test as very good, good, fair, poor, or unable to cooperate.

Once the SP leaves the room, follow the procedures outlined in Chapter 2, Section 2.3.2, Equipment Care and Maintenance Between SPs, to prepare the room for the next SP/exam.

### **3.3 Participant Report of Findings – Taste and Smell Testing**

A Report of Findings (Appendix C) will be generated and given to the participant during check-out. The report will not give an overall score result for the smell testing; however, the participant will be given the smell test results for the safety-sensitive items, smoke, and natural gas (a normal or diminished ability to smell these). ISIS will automatically generate the Report of Findings based on the participant's examination results for smell. The participant will also be given the taste test results for the ability to taste salt or bitter (a normal or diminished ability to taste these).

### 3.4 Comprehension or Language Difficulties

Some SPs may have difficulty understanding the examination instructions. If the SP cannot understand your instructions due to a developmental disability or other type of physical or mental impairment, ask if a family member or friend accompanied the SP to the MEC who can help explain your directions to the SP. If you still believe the SP cannot comprehend well enough for you to safely and accurately carry out the examination protocol, then on the ISIS screen code the appropriate section(s) as Could Not Obtain (CNO) and select “Communication Problem” as the reason for the Partial or Not Done exam status.

For many SPs, language barriers are a common cause of difficulty in understanding examination instructions. For Spanish-speaking SPs, if the examiner is not English-Spanish bilingual, a Spanish interpreter will be assigned to interpret for the SP and the examiner during the exam. If the SP speaks a language other than English or Spanish, arrangements will be made ahead of the Taste and Smell exam to identify an appropriate interpreter. If you cannot safely and accurately perform the exam on the SP due to a language barrier, then code the affected measure(s) as Could Not Obtain (CNO) on the ISIS screen and select “Language Barrier” as the reason for the Partial or Not Done exam status. See Chapter 5 of the MEC Operations Manual *Interpretation Guidelines* for procedures related to the interpretation of MEC examination components and working with interpreters.

### 3.5 Post-Examination Procedures

To end the component, click the Finish button on the ISIS screen. This signals the coordinator to make the next assignment for that SP. **Do not click Finish until the SP is completely ready to be escorted out of the room.** Wait for a message from the coordinator indicating where to direct the SP. Thank the SP for participating and accompany him or her to the next exam room or to the reception area.

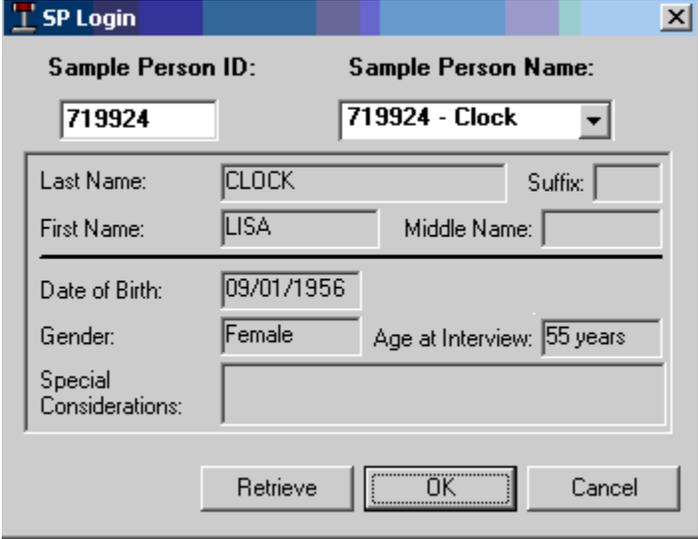
## 4. ISIS DATA ENTRY

### 4.1 General Screen Information

When the coordinator assigns an SP to the Taste and Smell room, a communication dialog box will appear on the ISIS computer screen. This will inform you that an SP has been assigned to this component. Click the Close button to remove the dialog box from the screen.

To begin the examination, click the “Logon SP” icon, the first icon on the left in the standard toolbar. ISIS will present a dialog box that asks for the name and password of the examiner. Wand the barcode on the SP’s identification bracelet or type the SP’s ID number to log the SP into the component. This will activate a dialog box (Exhibit 4-1) containing descriptive information about the SP (i.e., name, SP ID, age, etc.). Verify that the correct participant name appears on the screen. Contact the coordinator and MEC manager for assistance if the information in ISIS appears incorrect. Otherwise, click OK to initiate the examination.

Exhibit 4-1. Logon SP screen



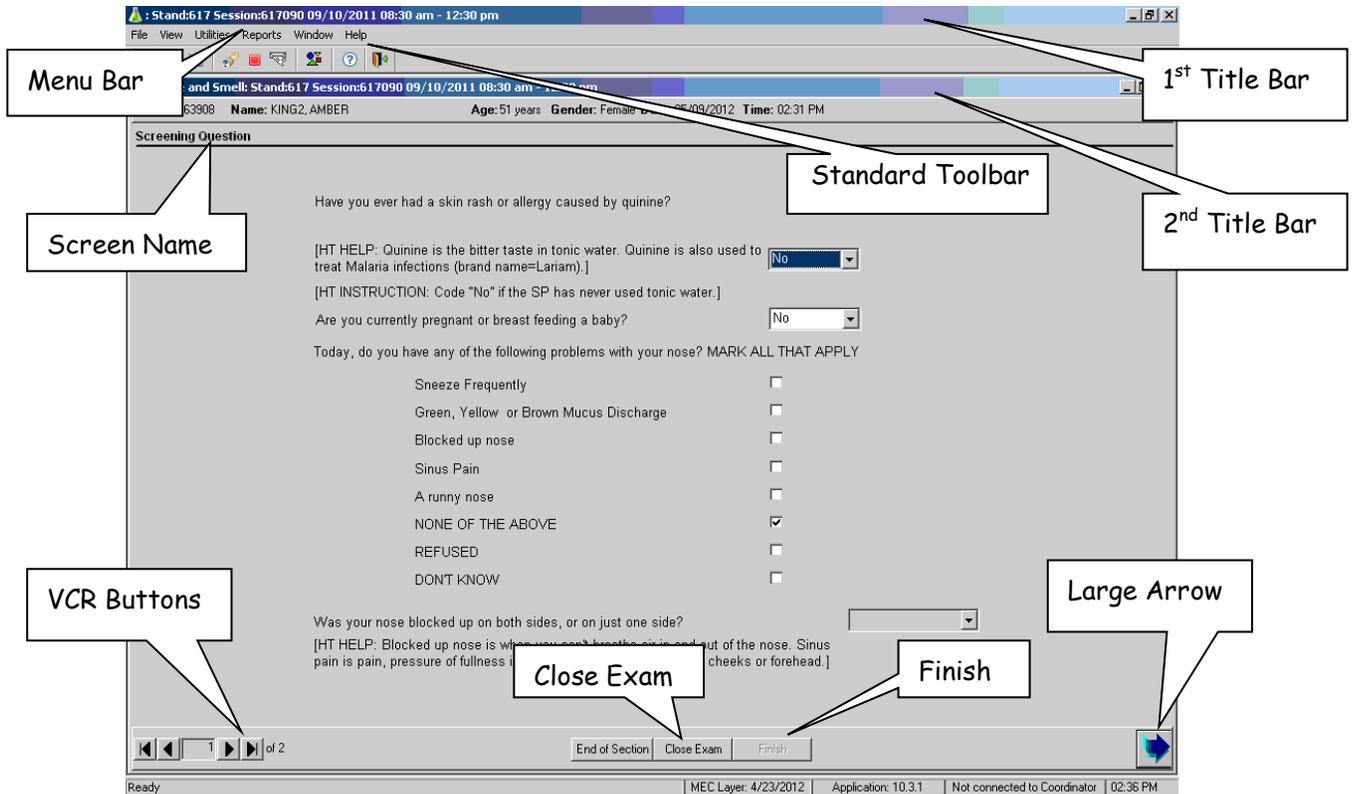
The screenshot shows a dialog box titled "SP Login". It contains the following fields and controls:

- Sample Person ID:** A text box containing "719924".
- Sample Person Name:** A dropdown menu showing "719924 - Clock".
- Last Name:** A text box containing "CLOCK".
- First Name:** A text box containing "LISA".
- Middle Name:** An empty text box.
- Suffix:** An empty text box.
- Date of Birth:** A text box containing "09/01/1956".
- Gender:** A text box containing "Female".
- Age at Interview:** A text box containing "55 years".
- Special Considerations:** An empty text box.
- Buttons:** "Retrieve", "OK", and "Cancel".

All ISIS screens have similar characteristics. As shown below (Exhibit 4-2), at the very top of the screen is a title bar containing the component name (Taste and Smell Subsystem), Stand number, Session number, and Session date and time. Below this are the Menu Bar and Standard Toolbar icons,

which provide software application commands and shortcuts. Under the standard toolbar sits a second title bar that identifies the examination component (Taste and Smell), Stand number, Session number, and Session date and time. Below the second title bar is the SP ID, Name, Age, Gender, and current date and time. The component screen name lies in the upper left of the main window area.

Exhibit 4-2. ISIS screen characteristics



At the bottom left corner of the screen is the ISIS screen number and a set of arrow buttons for navigating the screens: The far left button moves to the first screen and the far right button moves to the last screen. Directly beside the screen number, the left button moves to the previous screen and the right button moves to the next screen. At the bottom right corner of the screen is a large arrow. **Always click on the large arrow to advance to the next screen.**

In the middle of the bottom of the screen are two buttons: Close Exam and Finish. Clicking Close Exam will delete any data captured on the current screen, terminate the exam, and code the exam status as Partial or Not Done. **NEVER click the Close Exam button unless the exam must be discontinued and there is no other appropriate means to exit the application.** Click the Finish button

at the end of an exam. This sends a signal to the coordinator that the SP is available for the next assignment.

## 4.2 Screening Question Screen

The first screen in the ISIS Taste and Smell application is the Screening Question screen (Exhibit 4-3). In accordance with the Taste and Smell protocol, the screen will reflect different questions depending on the age and gender of the SP.

Exhibit 4-3. Screening question screen

Taste and Smell: Stand:617 Session:617090 09/10/2011 08:30 am - 12:30 pm

SP ID: 263908 Name: KING2, AMBER Age: 51 years Gender: Female Date: 05/03/2012 Time: 02:31 PM

Screening Question

Have you ever had a skin rash or allergy caused by quinine?

[HT HELP: Quinine is the bitter taste in tonic water. Quinine is also used to treat Malaria infections (brand name=Lariam).]

[HT INSTRUCTION: Code "No" if the SP has never used tonic water.]

Are you currently pregnant or breast feeding a baby?

Today, do you have any of the following problems with your nose? MARK ALL THAT APPLY

Sneeze Frequently

Green, Yellow or Brown Mucus Discharge

Blocked up nose

Sinus Pain

A runny nose

NONE OF THE ABOVE

REFUSED

DONT KNOW

Was your nose blocked up on both sides, or on just one side?

[HT HELP: Blocked up nose is when you can't breathe air in and out of the nose. Sinus pain is pain, pressure of fullness in the area of the face behind the cheeks or forehead.]

1 of 2

End of Section Close Exam Finish

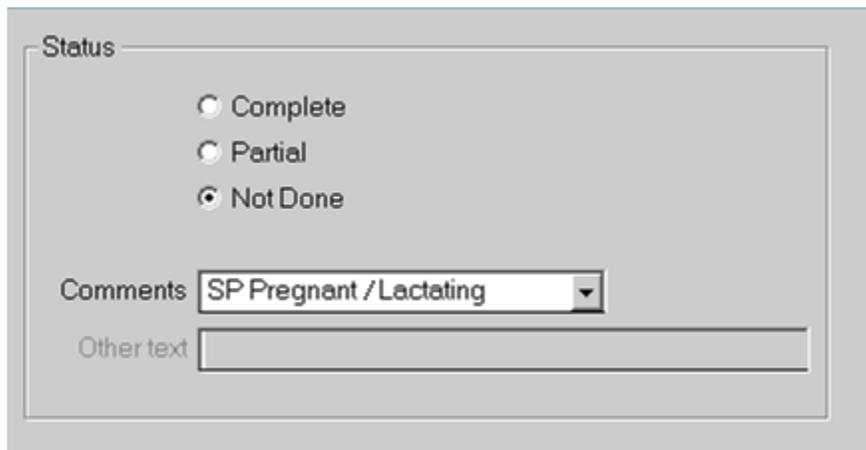
Pregnancy/breastfeeding question: Female SPs between the ages of 40-49

- Answering "Yes," "Refused," or "Don't Know" to the pregnancy/breastfeeding question will exclude the SP from the Taste and Smell component. The ISIS applications will set the component status to "Not Done," with a comment of "SP Pregnant/Lactating" (Exhibit 4-4).

History of quinine-related allergy question: All SPs

- Answering "Yes," "Refused," or "Don't Know" to the question that asks about a history of quinine-related allergy will exclude the SP from quinine taste testing but not from smell testing. The ISIS application will set the examination section status to "Partial" with a comment of "Safety Exclusion."

Exhibit 4-4. Component Status Not Done – SP pregnant/breastfeeding



The screenshot shows a form titled "Status" with three radio button options: "Complete", "Partial", and "Not Done". The "Not Done" option is selected. Below the status options is a "Comments" dropdown menu with the text "SP Pregnant / Lactating" visible. Below the dropdown menu is an "Other text" input field.

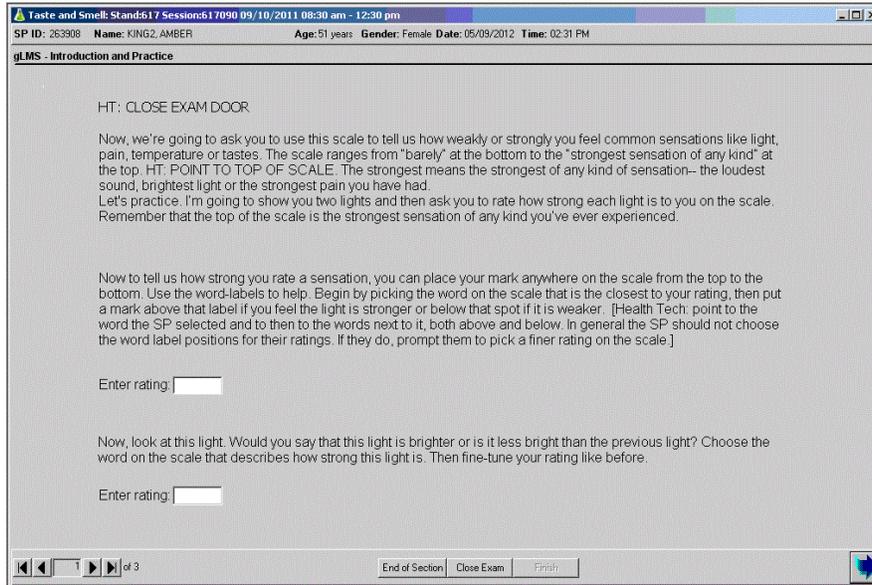
Nose conditions question list: All SPs 40 years and older

- The ISIS application will require you to mark at least one condition or "none of the above," "don't know," and "refused." Marking "blocked up nose" will enable the question, "Is your nose blocked up on both sides or on just one side."

### 4.3 gLMS Introduction and Practice Screen

This screen consists of general instructions and practice examples that use light intensity ratings. Use the number markings on the MEC version of the gLMS to enter the intensity ratings marked by the SP (Exhibit 4-5).

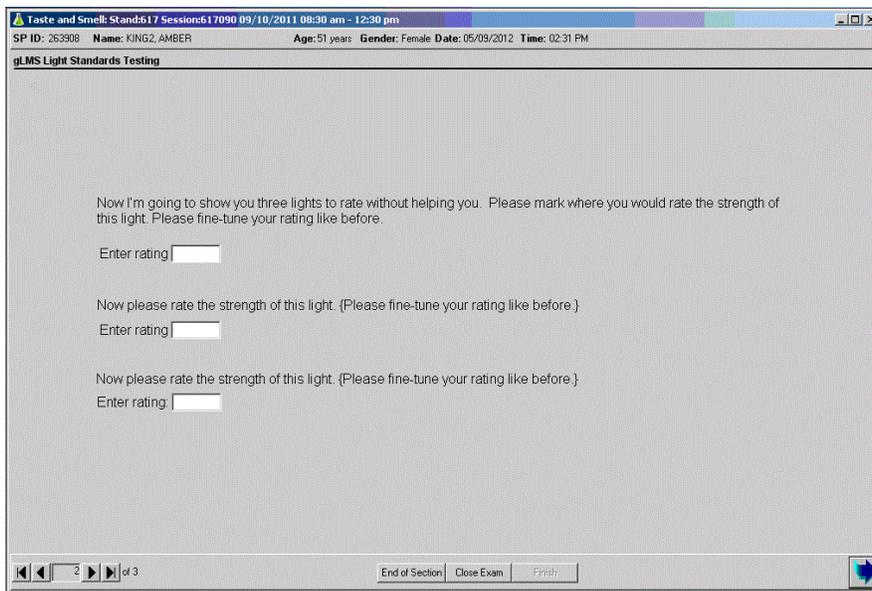
### Exhibit 4-5. gLMS Introduction and Practice screen



#### 4.4 gLMS Light Standards Testing Screen

This screen consists of instructions and data entry boxes for the three light standards. Use the number markings on the MEC version of the gLMS to enter the intensity ratings marked by the SP (Exhibit 4-6).

### Exhibit 4-6. gLMS Light Standards Testing screen



## 4.5 Taste Examination Screens

The first screen of the Taste Examination section is for the Tongue Tip Taste Test. There are up to two tastes to test: 1 mM quinine and 1 M salt (NaCl). Use the number markings on the MEC version of the gLMS to record, in ISIS, the intensity of the taste as marked by the SP. Also, in the same screen, record the SPs classification of the taste as salty, bitter, sour, no taste, or "something else" (Exhibit 4-7). The test will start with the one tip-of-the-tongue solution.

Exhibit 4-7. Tongue Tip Taste Test screen

Chemosensory: Stand:616 Session:616040 01/28/2011 08:30 am - 12:30 pm  
SP ID: 633351 Name: ZFG, MOM Age: 50 years Gender: Female Date: 12/20/2011 Time: 03:47 PM  
Taste Examination Screen (Tip of Tongue)

Painted across the tip of the tongue

Tastant	Strength of Taste	Description of Taste
	<input type="text" value="40"/>	<input type="radio"/> Salty <input checked="" type="radio"/> Bitter <input type="radio"/> Sour <input type="radio"/> Something Else <input type="radio"/> No Taste
	<input type="text" value="40"/>	<input checked="" type="radio"/> Salty <input type="radio"/> Bitter <input type="radio"/> Sour <input type="radio"/> Something Else <input type="radio"/> No Taste

1 of 3  
End of Section Close Exam Finish

The second screen of the Taste Examination section is for the Whole Mouth Solution Taste Test. Two sequences of the presentation order of the salt and quinine tastants will be used. Each participant will be assigned to have one of these test sequences and the test sequence will be assigned on a random basis by the ISIS system. Version "A" (Exhibit 4-8) begins with the orange vial (1 M NaCl) followed by the blue (1 mM quinine) and ending with the yellow (0.32 M NaCl). Version "B" (Exhibit 4-9) starts with the yellow vial, followed by the blue and ending with the orange. For each tastant, use the number markings on the MEC version of the gLMS to record, in ISIS, the intensity of the taste as marked

by the SP. Also, in the same screen, record the SPs classification of the taste as: salty, bitter, sour, no taste, or “something else.”

Exhibit 4-8. Whole Mouth Solution Taste Test screen – Version A

Chemosensory: Stand:616 Session:616040 01/28/2011 08:30 am - 12:30 pm  
SP ID: 633351 Name: ZFG, MOM Age: 50 years Gender: Female Date: 12/20/2011 Time: 03:47 PM

Taste Examination Screen (Sipped)

Whole Mouth Taste

Tastant	Strength of Taste	Description of Taste
	80	<input checked="" type="radio"/> Salty <input type="radio"/> Bitter <input type="radio"/> Sour <input type="radio"/> Something Else <input type="radio"/> No Taste
	50	<input checked="" type="radio"/> Salty <input type="radio"/> Bitter <input type="radio"/> Sour <input type="radio"/> Something Else <input type="radio"/> No Taste
	20	<input checked="" type="radio"/> Salty <input type="radio"/> Bitter <input type="radio"/> Sour <input type="radio"/> Something Else <input type="radio"/> No Taste

End of Section Close Exam Finish

Exhibit 4-9. Whole Mouth Solution Taste Test screen – Version B

Chemosensory: Stand:616 Session:616040 01/28/2011 08:30 am - 12:30 pm  
SP ID: 633351 Name: ZFG, MOM Age: 50 years Gender: Female Date: 12/20/2011 Time: 03:47 PM

Taste Examination Screen (Sipped)

Whole Mouth Taste

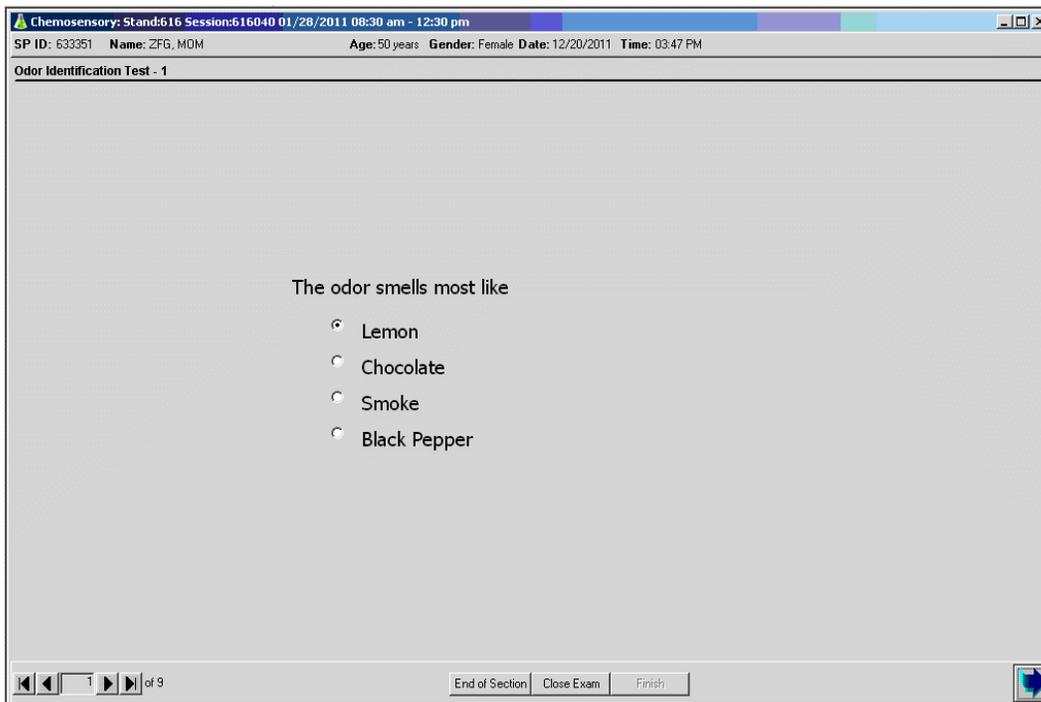
Tastant	Strength of Taste	Description of Taste
	20	<input checked="" type="radio"/> Salty <input type="radio"/> Bitter <input type="radio"/> Sour <input type="radio"/> Something Else <input type="radio"/> No Taste
	50	<input checked="" type="radio"/> Salty <input type="radio"/> Bitter <input type="radio"/> Sour <input type="radio"/> Something Else <input type="radio"/> No Taste
	80	<input checked="" type="radio"/> Salty <input type="radio"/> Bitter <input type="radio"/> Sour <input type="radio"/> Something Else <input type="radio"/> No Taste

End of Section Close Exam Finish

## 4.6 Odor Identification Test Screens

This section includes one screen per odor and will contain a place to indicate what the odor smells most like as illustrated in Exhibits 4-10 through 4-17. In accordance with the Taste and Smell protocol, the ISIS applications will require the SP to choose one of the four alternative smells from each screen.

Exhibit 4-10. Odor Identification screen – item 1



The screenshot shows a web-based application window titled "Chemosensory: Stand:616 Session:616040 01/20/2011 08:30 am - 12:30 pm". The user information at the top includes "SP ID: 633351", "Name: ZFG, MDM", "Age: 50 years", "Gender: Female", "Date: 12/20/2011", and "Time: 03:47 PM". The main content area is titled "Odor Identification Test - 1" and contains the question "The odor smells most like" followed by four radio button options: "Lemon", "Chocolate", "Smoke", and "Black Pepper". The "Lemon" option is selected. At the bottom, there is a navigation bar with "End of Section", "Close Exam", and "Finish" buttons, and a status indicator showing "1 of 9".

Chemosensory: Stand:616 Session:616040 01/20/2011 08:30 am - 12:30 pm

SP ID: 633351 Name: ZFG, MDM Age: 50 years Gender: Female Date: 12/20/2011 Time: 03:47 PM

Odor Identification Test - 1

The odor smells most like

- Lemon
- Chocolate
- Smoke
- Black Pepper

1 of 9 End of Section Close Exam Finish

Exhibit 4-11. Odor Identification screen – item 2

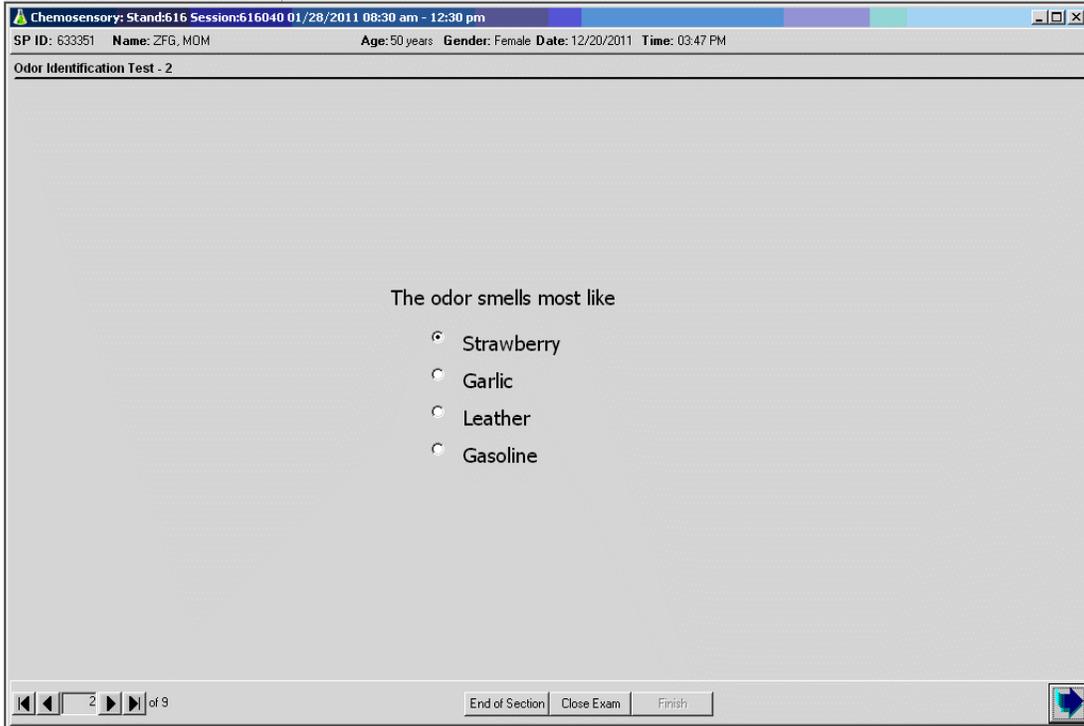


Exhibit 4-12. Odor Identification screen – item 3

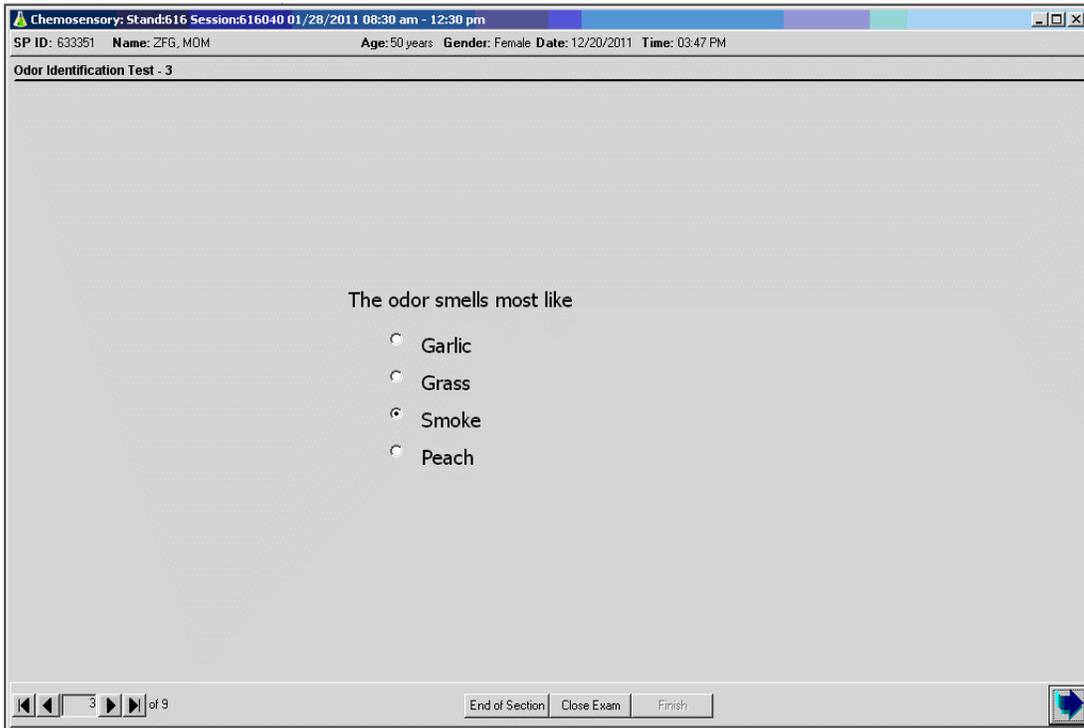


Exhibit 4-13. Odor Identification screen – item 4

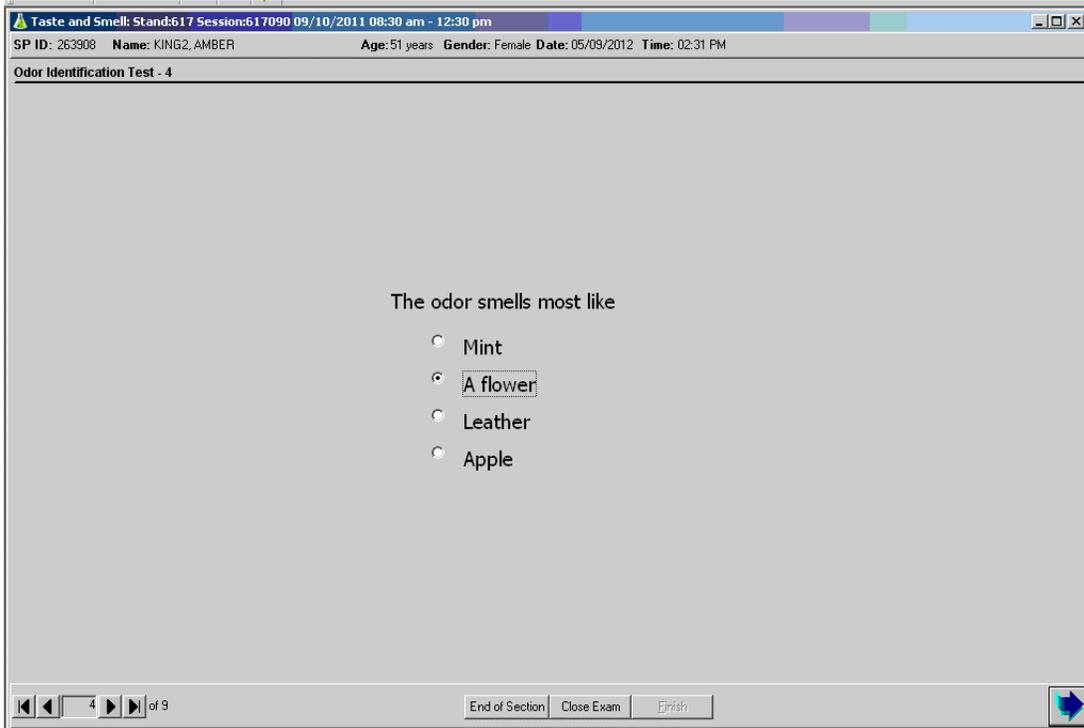


Exhibit 4-14. Odor Identification screen – item 5

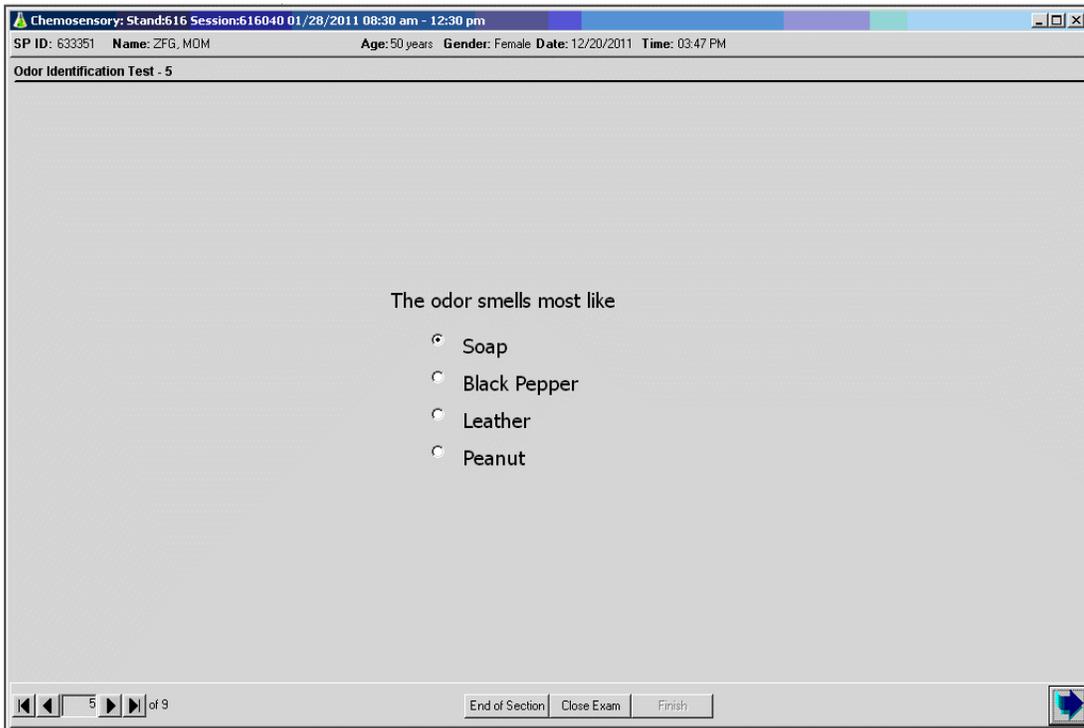


Exhibit 4-15. Odor Identification screen – item 6

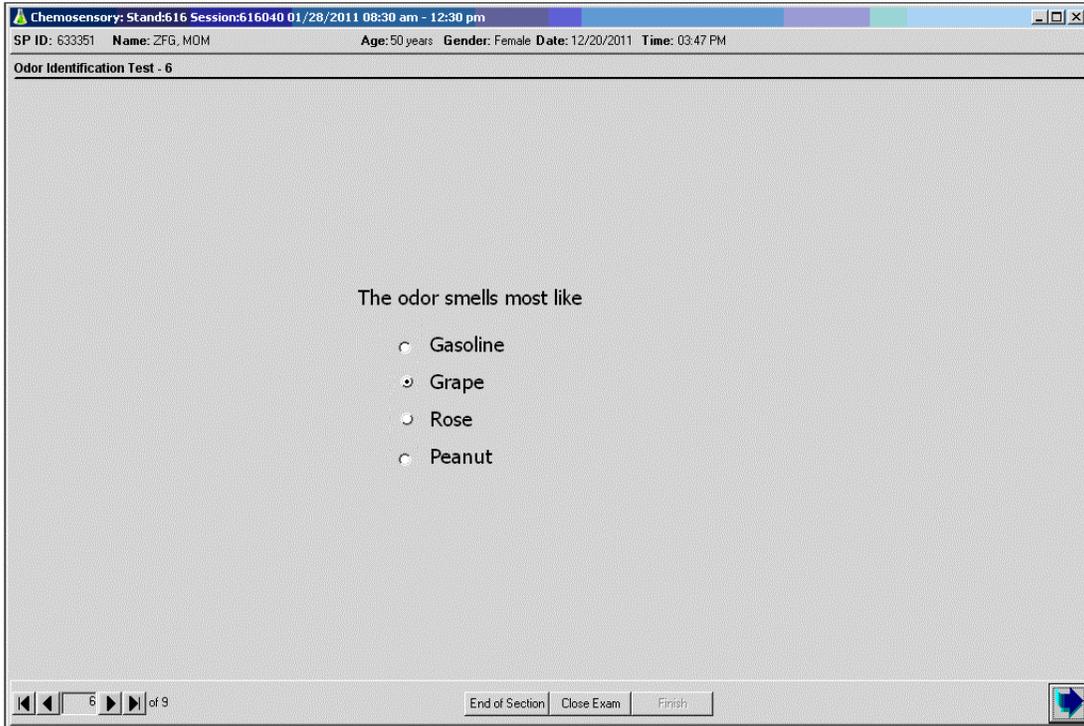


Exhibit 4-16. Odor Identification screen – item 7

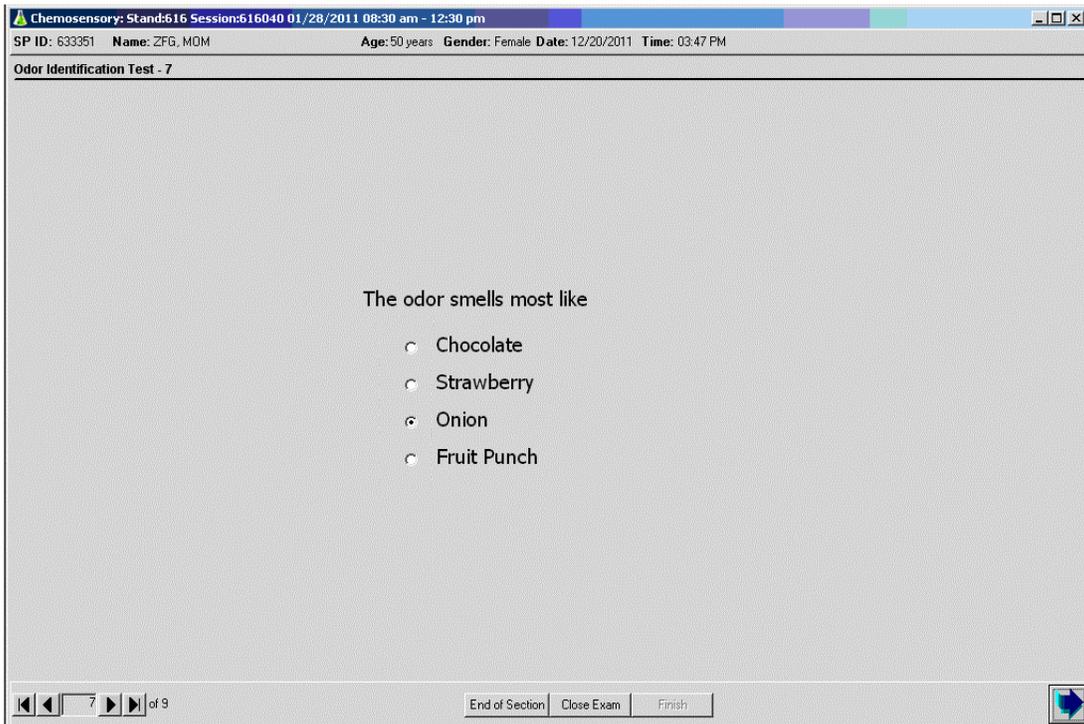
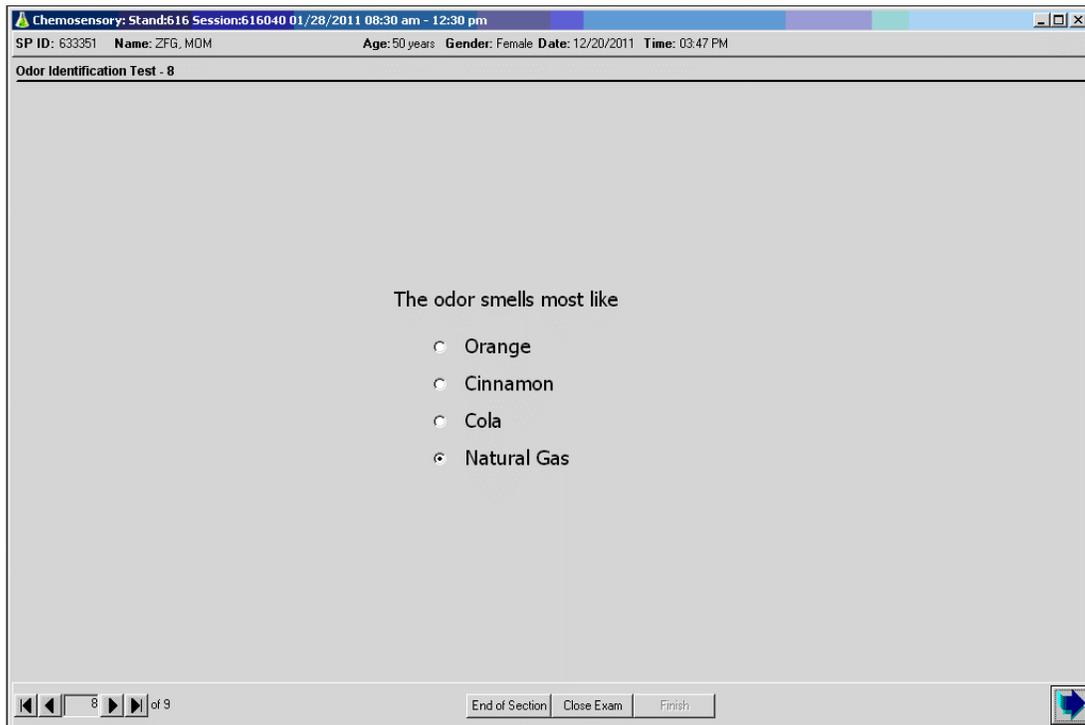


Exhibit 4-17. Odor Identification screen – item 8



#### 4.7 Whole Mouth Solution Replicate Taste Test

This section includes the replicate whole mouth solution portion of the taste test. The SP will be randomly selected by ISIS to receive either the 1 M NaCl (Exhibit 4-18) or the 0.32 M NaCl test solution (Exhibit 4-19).

Exhibit 4-18. Replicate Whole Mouth Taste Test “A”

Chemosensory: Stand:616 Session:616040 01/28/2011 08:30 am - 12:30 pm

SP ID: 633351 Name: ZFG, MOM Age: 50 years Gender: Female Date: 12/20/2011 Time: 03:47 PM

Single Replicate Taste Test

Single Replicant Taste

Tastant	Strength of Taste	Description of Taste
	<input type="text" value="80"/>	<input checked="" type="radio"/> Salty <input type="radio"/> Bitter <input type="radio"/> Sour <input type="radio"/> Something Else <input type="radio"/> No Taste

2 of 3

End of Section Close Exam Finish

Exhibit 4-19. Replicate Whole Mouth Taste Test “B”

Chemosensory: Stand:616 Session:616040 01/28/2011 08:30 am - 12:30 pm

SP ID: 633351 Name: ZFG, MOM Age: 50 years Gender: Female Date: 12/20/2011 Time: 03:47 PM

Single Replicate Taste Test

Single Replicant Taste

Tastant	Strength of Taste	Description of Taste
	<input type="text" value="30"/>	<input checked="" type="radio"/> Salty <input type="radio"/> Bitter <input type="radio"/> Sour <input type="radio"/> Something Else <input type="radio"/> No Taste

1 of 2

End of Section Close Exam Finish

## 4.8 SP's Understanding of the Test Screen

This screen is for the health technologist to rate the SP's understanding of the exam and cooperation with the exam. Use the drop-down list to select: Very Good, Good, Fair, Poor, or Unable to cooperate (Exhibit 4-20).

Exhibit 4-20. SP's understanding of the test screen

Chemosensory: Stand615 Session:615731 11/07/2010 01:30 pm - 05:30 pm

SP ID: 566970 Name: AMINI, MITUL Age: 52 years Gender: Female Date: 04/08/2011 Time: 11:54 AM

Exam SP Comment

Please rate SP's understanding of and cooperation with exam procedures.

Very Good  
Good  
Fair  
Poor  
Unable to Cooperate

1 of 2

End of Section Close Exam Finish

## 4.9 Taste and Smell Component Status Screen

The Taste and Smell Component Status marks the final ISIS screen. The purpose of this screen is to document the overall status of the Taste and Smell examination: Complete, Partial, and Not Done. As with all other MEC exam components, ISIS will automatically default to one of these codes.

- **Complete:** All sections were completed in ISIS (Exhibit 4-21).
- **Partial:** One or more sections were NOT completed in ISIS (Exhibit 4-22).
- **Not Done:** All sections were NOT completed in ISIS (Exhibit 4-23).

For Partial and Not Done exams, use the drop-down menu beside the Comments box to select from a list of reasons that include safety exclusion, SP refusal, no time, physical limitation, communication problem, equipment failure, SP ill/emergency, interrupted, medical appliance, SP pregnant, prescription medication, and Other, specify. If you choose the “Other, specify” comment you must enter a description. Be as brief as possible, a maximum of 40 characters are allowed. Only select “Other, specify” if the comment does not fit into one of the defined comments.

Exhibit 4-21. Component status screen – Complete

Chem sensory: Stand615 Session615731 11/07/2010 01:30 pm - 05:30 pm  
SP ID: 566970 Name: AMINI, MITUL Age: 52 years Gender: Female Date: 04/08/2011 Time: 11:54 AM

Component Status

Status

Complete  
 Partial  
 Not Done

Comments

Other text

End of Section Close Exam Finish

Exhibit 4-22. Component status screen – Partial

The screenshot shows a software window titled "Chemosensory Standards Session 615731 11/07/2010 01:30 pm - 05:30 pm". The window contains a form for "Component Status". At the top, it displays "SP ID: 569370 Name: AMINI, MTUL Age: 52 years Gender: Female Date: 04/08/2011 Time: 11:54 AM". The main form area has a "Status" section with three radio buttons: "Complete", "Partial" (which is selected), and "Not Done". Below this is a "Comments" section with a dropdown menu showing "SP Refusal" and an "Other text" input field. At the bottom of the window, there are navigation buttons: "End of Session", "Close Exam", and "Finish".

Exhibit 4-23. Component status screen – Not Done

The screenshot shows the same software window as Exhibit 4-22. In this instance, the "Not Done" radio button is selected. The "Comments" dropdown menu now shows "SP Pregnant". The "Other text" input field remains empty. The "End of Session", "Close Exam", and "Finish" buttons are still visible at the bottom.

Lastly, click “Finish” to end the examination. Wait for a message from the coordinator indicating where to direct the SP. Thank the SP for participating and escort him or her to the next exam room or to the coordinator.

#### 4.10 Edit Check Boxes

As you proceed through the examination, certain ISIS entries will activate soft edit warnings and or hard edit errors.

Soft edits are limits imposed by the system that serve as an alert for possible data entry keying errors. If a value is outside predefined edit limits, ISIS will display a message warning that the value appears to be outside the normally expected range of values for that item. The HTs have the option of editing or accepting that data value. The following soft edits were placed on the gLMS Training Screen (Exhibit 4-24):

- If the rating for the “Brightness of light of intermediate low intensity” is greater or equal than the rating for the “Brightness of light of intermediate high intensity.”

Exhibit 4-24. Soft Edit Warning



- Apparently illogical values; for example if a description of taste was selected as “Salty,” “Bitter,” or “Sour” and a gLMS rating of zero was entered (Exhibit 4-25).

Exhibit 4-25. Soft Edit Description of Taste



- If the SP is showing label choice preference when they use the gLMS scale (Exhibit 4-26).

Exhibit 4-26. Soft Edit Label preference



Hard edit errors are limits imposed by the application that required a data value or prevent data entry outside the expected range. The following are examples of hard edits that were placed on the Taste and Smell application.

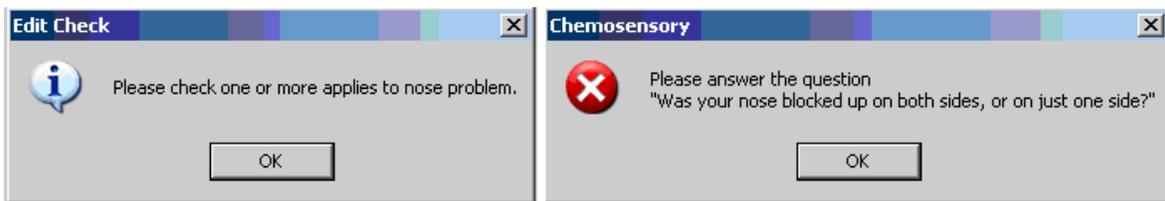
- If an answer is not selected for the following questions (Exhibit 4-27):
  - Are you currently pregnant or currently breast feeding a baby?

Exhibit 4-27. Hard Edit Exclusion Questions



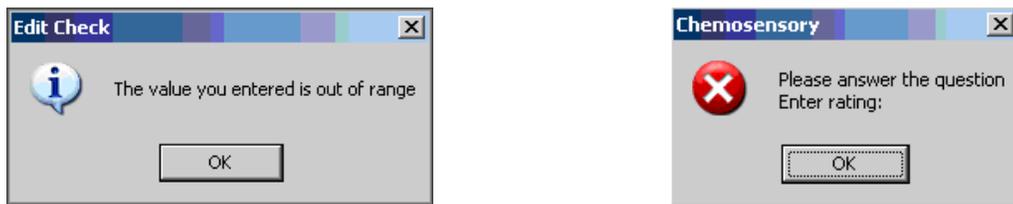
- If a condition is not selected from the screening questions screen that describes the condition of the participant's nose (Exhibit 4-28).

Exhibit 4-28. Hard Edit Screening Questions



- If a data value exceeds the range of the gLMS (i.e., it is greater than 100) and/or if an expected value is missing (Exhibit 4-29).

Exhibit 4-29. Hard Edit gLMS



## **5. QUALITY CONTROL**

### **5.1 Introduction to Quality Control**

Quality control procedures ensure the collection and documentation of accurate, reliable data. The procedures were developed to reduce interexaminer variability, reduce error, and ensure data quality. The quality control program for this component will take place in mobile examination centers (MECs) and will consist of the following major elements:

- Training;
- Monitoring equipment and equipment repair, and verifying daily and weekly calibrations; and
- Site visit observations by NCHS and Westat.

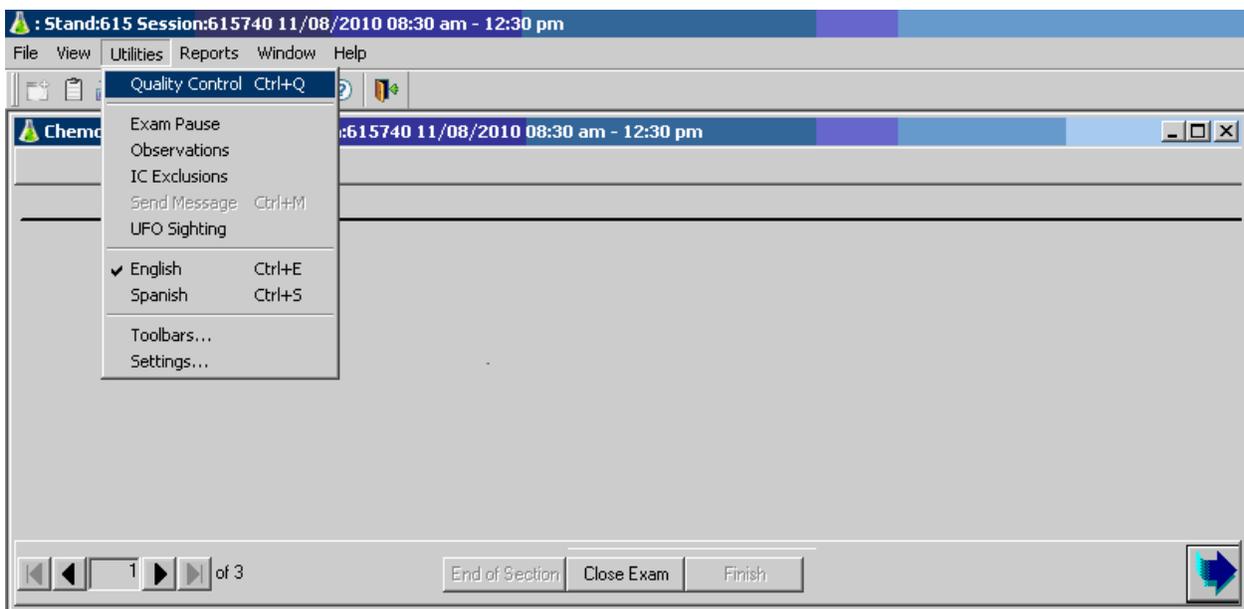
### **5.2 Training**

Training will be provided by NCHS personnel, Westat, and an independent expert consultant. This training process includes didactic presentations and practice session with volunteers. Ongoing training needs, as identified by the home office staff and NCHS, will be assessed and scheduled. Retraining sessions will be arranged by the Westat component specialist in coordination with the NCHS project officer and the chemosenses consultants when major protocol changes are introduced, or when a lack of standardization is observed among the technologists.

### 5.3 Monitoring Equipment and Equipment Repair

Routine cleaning of the taste and smell equipment is an essential quality control measure in order to ensure optimal operation. Specifically, the Porto Dent II and canister must be cleaned and disinfected according to the schedule outlined in this section. The technologist will complete these procedures using the Chemosenses Quality Control Checks dialog box that contains designated tabs for the Start of Stand, Daily, Start of Session, End of Session, and End of Stand. To access this dialog box, select the Quality Control Checks option from the toolbar menu at the top of the screen (Exhibit 5-1). Click the “Done” box beside each of the checked items listed to record completion of the procedure. If the QC procedures have not been completed for that time period, a message will be displayed at each logon until the QC procedures have been completed for that time period. The home office component staff monitors the equipment QC completion rates, and provides feedback and/or retraining as warranted.

Exhibit 5-1. Quality Control Checks



### 5.3.1 Quality Control Checks Screens

The schedule for equipment cleaning is provided in the following screens of the Quality Control Checks dialog box.

- **Start of Stand (Exhibit 5-2)**
  - Clean the surface of the Porto-Dent;
  - Clean the surface of the microphone stand;
  - Clean the oral funnel cup; and
  - Test the functioning of the vacuum.

Exhibit 5-2. Start of Stand QC Checks

The screenshot shows a software window titled "Chemosensory Quality Control Checks" with a close button (X) in the top right corner. The window has four tabs: "Start of Stand", "Start of Session", "End of Session", and "End of Stand". The "Start of Stand" tab is selected. The main area contains a table with three columns: "QC Check", "Done", and "Comment".

QC Check	Done	Comment
Clean the surface of the Porto-Dent	<input type="checkbox"/>	
Clean the surface of the microphone stand	<input type="checkbox"/>	
Clean the oral funnel cup	<input type="checkbox"/>	
Test the functioning of the vacuum	<input type="checkbox"/>	

At the bottom right of the window are two buttons: "OK" and "Cancel".

- Start of Session (Exhibit 5-3)
  - Clean the surface of the Porto-Dent;
  - Clean the surface of the microphone stand;
  - Clean the oral funnel cup; and
  - Test the functioning of the vacuum.

Exhibit 5-3. Start of Session QC Checks

QC Check	Done	Comment
Clean the surface of the Porto-Dent	<input type="checkbox"/>	
Clean the surface of the microphone stand	<input type="checkbox"/>	
Clean the oral funnel cup	<input type="checkbox"/>	
Test the functioning of the vacuum	<input type="checkbox"/>	

- Daily (Exhibit 5-4)
  - Click the “Done” box beside “Luminance at high level;”
  - Press and hold the HIGH button on the control box of the light source;
  - Turn the Lux meter ON;
  - Press the RANGE button to switch the range to 0.00;
  - Hold the lux meter at the surface of the LCD panel (P reading);
  - Record the results in the “Results” field in ISIS;
  - Press the RANGE button to switch the range to .000;
  - Hold the light meter at the SP mark (SP reading);
  - Record the results in the “Comment” field in ISIS; and
  - Follow the steps above for the intermediate high level (MHI), medium level (MED), intermediate low level (MLO), low level (LOW), and the background level.

Exhibit 5-4. Daily QC Checks

QC Check	Done	Result	Comment
Luminance at intermediate low level	<input type="checkbox"/>		
Luminance at intermediate high level	<input type="checkbox"/>		
Luminance at medium level	<input type="checkbox"/>		
Luminance at low level	<input type="checkbox"/>		
Luminance at high level	<input type="checkbox"/>		
Luminance at the background level	<input type="checkbox"/>		

- End of Session (Exhibit 5-5)
  - Empty all fluid out of the vacuum line;
  - Remove the full canister and install the empty one;
  - Empty and rinse the canister;
  - Mix one packet of VacuKleen E2 with 1 quart of warm tap water;
  - Slowly run all of the VacuKleen solution through the vacuum line;
  - Empty and rinse the canister; and
  - Inspect the HVE valve for residue.

Exhibit 5-5. End of Session QC Checks

QC Check	Done	Comment
Empty all fluid out of the vacuum line	<input type="checkbox"/>	
Remove the full canister and install the empty one.	<input type="checkbox"/>	
Empty and rinse the canister	<input type="checkbox"/>	
Mix one packet of VacuKleen E2 with 1 quart of warm tap water.	<input type="checkbox"/>	
Slowly run all of the VacuKleen solution through the vacuum line	<input type="checkbox"/>	
Empty and rinse the canister	<input type="checkbox"/>	
Inspect the HVE valve for residue.	<input type="checkbox"/>	

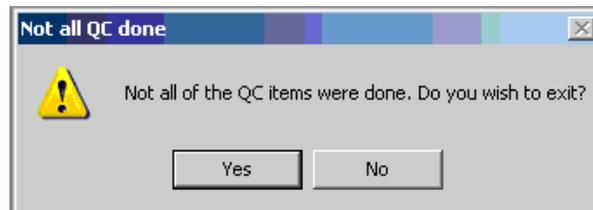
- End of Stand (Exhibit 5-6)
  - Empty all fluid out of the vacuum line;
  - Mix two packets of VacuKleen E2 with 2 quarts of warm tap water;
  - Run 1 quart through each vacuum line;
  - Insert vacuum line plugs into the ends of both vacuum lines;
  - Remove and clean the HVE valve;
  - Empty, rinse, and dry both canisters;
  - Clean the surface of the Porto-Dent;
  - Clean the surface of the microphone stand; and
  - Clean the oral funnel cup.

Exhibit 5-6. End of Stand QC Checks

QC Check	Done	Comment
Empty all fluid out of the vacuum line	<input type="checkbox"/>	
Mix two packets of VacuKleen E2 with 2 quarts of warm tap water	<input type="checkbox"/>	
Run 1 quart through each vacuum line	<input type="checkbox"/>	
Insert vacuum line plugs into the ends of both vacuum lines	<input type="checkbox"/>	
Remove and clean the HVE valve	<input type="checkbox"/>	
Empty, rinse and dry both canisters	<input type="checkbox"/>	
Clean the surface of the Porto-Dent	<input type="checkbox"/>	
Clean the surface of the microphone stand	<input type="checkbox"/>	
Clean the oral funnel cup	<input type="checkbox"/>	

When finished completing the required Quality Control Checks, click “OK” to exit the dialog box and return to the main component screen. However, if you have not checked the “Done” box beside all of the required checks, clicking “OK” will open the following pop-up window (Exhibit 5-7).

Exhibit 5-7. Quality Control Checks – Not Done QC



### 5.3.2 Equipment Maintenance

Each MEC will be furnished with one Porto Dent II and two canisters. A backup Porto Dent II will also be kept at the home office for training. If a Porto Dent II in the field becomes disabled, document the problem in the UFO system and contact the chief technologist, MEC manager, and Westat component specialist immediately. Westat will arrange to send the backup unit to the field by overnight delivery. The component specialist will also coordinate with the MEC team to send the malfunctioning unit for repair.

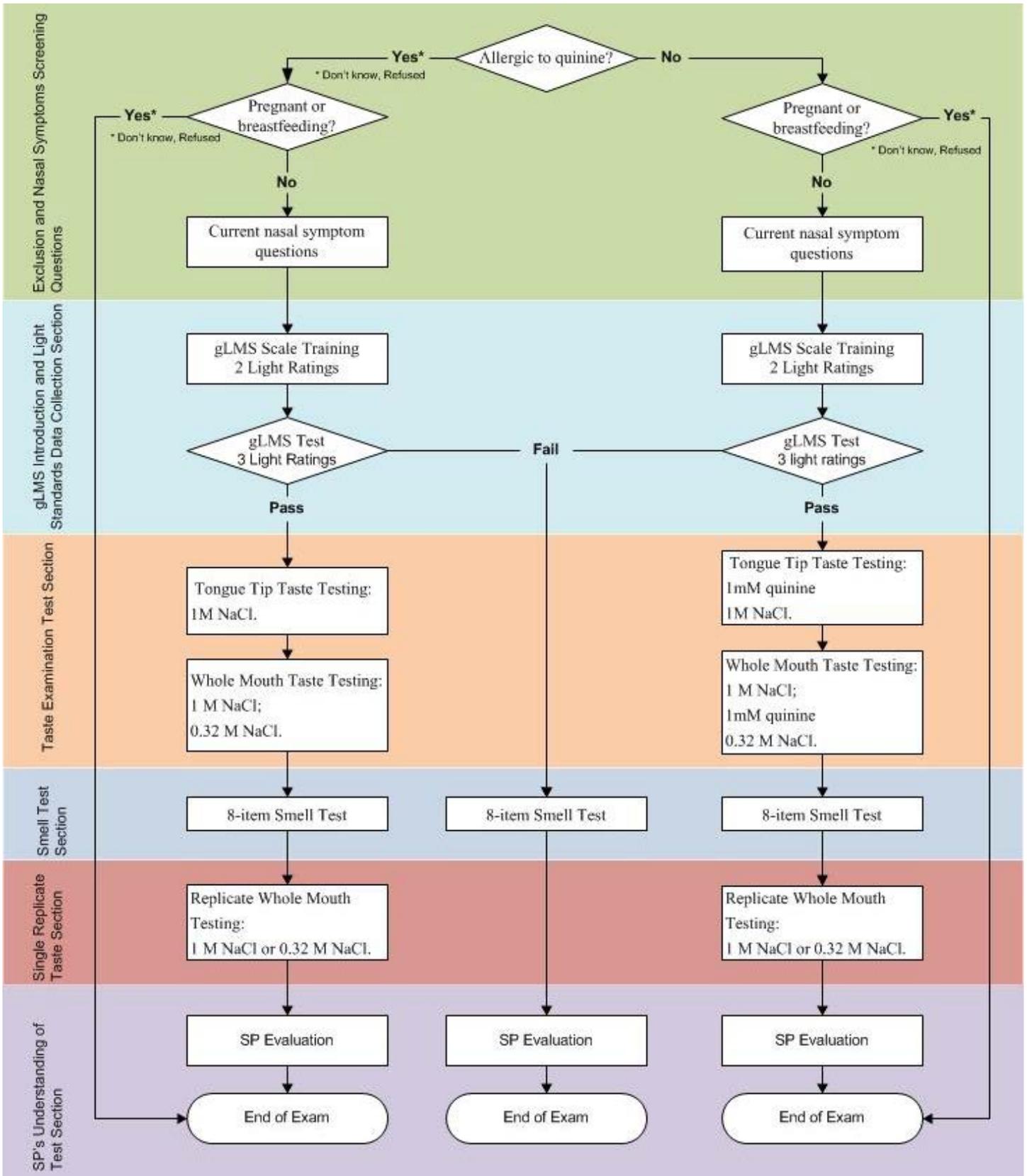
### 5.4 Site Visit Observations

NCHS personnel, Westat component staff, and the taste and smell consultants will visit the MEC team at regular intervals to observe taste and smell examinations. To further monitor the quality of data collection, Westat component staff will generate reports from the ISIS intraweb. The number of taste and smell examinations and examination times: cumulative and sorted by session, by age group, and by technologist, as well as the reason for not done and partial examinations, will be analyzed for the pilot.

APPENDIX A

EXAM FLOW

## APPENDIX A. EXAM FLOW



**APPENDIX B**

**TALKING POINTS**

## General Introduction to the Taste & Smell Component

### ***PLACE APPLICATORS INTO THE ORANGE AND BLUE VIALS***

- Two tests--Taste and smell.
- Before we begin I will ask you a few questions.

### ***ADMINISTER PRE-EXAM SCREENING QUESTIONS***



## Introduction to Taste Testing

- Purpose – Measure how strongly you taste some common tastes.
- I'll have you taste up to six samples based on how you answered my questions.
  - The first tastes are put on the tip of your tongue.
  - For the others you swish the taste in your mouth without swallowing.
- Rate how strong the taste is.
- Identify the taste.

### ***ADMINISTER INTRO TO gLMS SCALE & LIGHT TESTS***



## Instructions for the Tongue Tip Taste Test

### ***PUT ON GLOVES – ASK SP TO RINSE***

- Apply taste samples across the tip of your tongue (show picture).
- Rate how strong the taste is before you put your tongue back into your mouth.
- Tell me what the taste is.
- **Rinse before we start and after each test.**

## APPENDIX B. TALKING POINTS

### Instructions for the Whole Mouth Taste Test

- Take all of this solution into your mouth but **DON'T SWALLOW.**
- Gently swish it around for about 3 seconds.
- Spit it out.
- Rate how strong the taste is.
- Tell us what the taste is.
- **Rinse after each test with water.**
- If you get a taste that is too strong or unpleasant I will give you a rinse to stop the taste.

### Instructions for the Smell Test

- Purpose – To see how well you can identify some common smells.
- Two cards
  - Each card has 4 smells.
  - Each smell has 4 choices.
  - Look at the four choices while I read them to you.
  - Tell me which choice is what you smelled.
    - If not sure, pick the closest.
    - If no smell, guess.

### Instructions for the Replicate Taste Test

#### ***ASK SP TO RINSE***

- Take all of this solution into your mouth but **DON'T SWALLOW.**
- Gently swish it around for about 3 seconds.
- Spit it out.
- Rate how strong the taste is.
- Tell us what the taste is.
- Rinse after the test with water.
- If you get a taste that is too strong or unpleasant I will give you a rinse to stop the taste.

## **General Introduction to the Taste & Smell Component** **(Spanish)**

### ***PLACE APPLICATORS INTO THE ORANGE AND BLUE VIALS***

- Dos pruebas—Gusto y olfato.
- Antes de empezar le haré algunas preguntas.

### ***ADMINISTER PRE-EXAM SCREENING QUESTIONS***



## **Introduction to Taste Testing**

- Propósito – Medir qué tan fuertemente siente el sabor de algunos sabores comunes.
- Le pediré que pruebe hasta seis muestras dependiendo cómo responde mis preguntas.
  - Le pondré los primeros sabores en la punta de la lengua.
  - Para los otros debe mover la muestra en la boca sin pasársela.
- Califique qué tan fuerte es el sabor.
- Identifique el sabor.

### ***ADMINISTER INTRO TO gLMS SCALE & LIGHT TESTS***



## **Instructions for the Tongue Tip Taste Test**

### ***PUT ON GLOVES – ASK SP TO RINSE***

- Ponga las muestras de los sabores en la punta de la lengua (show picture).
- Antes de poner la lengua dentro de la boca, califique qué tan fuerte es el sabor.
- Dígame qué sabor es.
- **Enjuáguese la boca antes de empezar y después de cada prueba.**

### **Instructions for the Whole Mouth Taste Test**

- Póngase toda esta solución dentro de la boca, pero **NO SE LA PASE.**
- Suavemente muévela dentro de la boca por 3 segundos más o menos.
- Escúpala.
- Califique qué tan fuerte es el sabor.
- Díganos qué sabor es.
- **Enjuáguese la boca con agua después de cada prueba.**
- Si algún sabor le resulta demasiado fuerte o desagradable, yo le daré un enjuague para hacer que el sabor pase.

### **Instructions for the Smell Test**

- Propósito – Ver qué tan bien puede identificar algunos olores comunes.
- Dos tarjetas
  - Cada tarjeta tiene 4 olores.
  - Cada olor tiene 4 opciones.
  - Mire las cuatro opciones mientras se las leo.
  - Dígame cuál opción es la que usted olió.
    - Si no está seguro(a) escoja la más cercana.
    - Si no olió nada, adivine.

### **Instructions for the Replicate Taste Test**

#### ***ASK SP TO RINSE***

- Póngase toda esta solución dentro de la boca, pero **NO SE LA PASE.**
- Suavemente muévela dentro de la boca por 3 segundos más o menos.
- Escúpala.
- Califique qué tan fuerte es el sabor.
- Díganos qué sabor es.
- Enjuáguese la boca con agua después de la prueba.
- Si algún sabor le resulta demasiado fuerte o desagradable yo le daré un enjuague para hacer que el sabor pase.

APPENDIX C

REPORT OF FINDINGS

## APPENDIX C. ROF

### 2012 Taste and Smell Report of Findings

#### Smell Test Results:

1. Your ability to smell smoke was normal / Your ability to smell smoke was diminished}.
2. Your ability to smell natural gas was normal / Your ability to smell natural gas was diminished}.

#### Taste Test Results:

1. Salty Taste: Your ability to taste salt was normal / Your ability to taste salt was diminished / You were unable to taste salt.

[If diminished salty taste, insert this text here: {Your ability to taste salt may have been less than normal because of a temporary problem such as with a medication that you take. If the problem persists, you may want to speak with your doctor to see if there is a medical problem affecting your sense of salty taste. }]

[If unable to taste salt taste, insert this text here: {You may have been unable to taste salt because of a temporary problem such as with a medication that you take. If the problem persists, you may want to see your doctor to see if there is a medical problem affecting your salty taste. }]

2. Bitter Taste: Your ability to taste bitter was normal / Your ability to taste bitter was diminished / You were unable to taste bitter}.

[If ability to taste bitter is diminished, insert this text here: {Your ability to taste bitter may have been less than normal because of a temporary problem such as with a medication that you take. If the problem persists, you may want to speak with your doctor to see if there is a medical problem affecting your bitter taste.}]

[If unable to taste bitter, insert text here: {You were unable to taste bitter at the time of your exam. This may have been due to temporary problem such as with a medication that you take. If the problem persists, you may want to see your doctor to see if there is a medical problem affecting your bitter taste. }]

For further information on problems with taste and smell, you can visit these National Institutes of Health web sites:

For Information on Problems with Your Sense of Smell:

<http://www.nidcd.nih.gov/health/smelltaste/pages/smell.aspx>

For Information on Problems with Your Sense of Taste:

<http://www.nidcd.nih.gov/health/smelltaste/pages/taste.aspx>

APPENDIX D

DAILY QC CHECKS

LIGHT SOURCE

## APPENDIX D. DAILY QC CHECKS

The calibration of the light source will be verified daily using the Hanna Portable Lux Meter. Exposure measurements will be taken at the surface of the LCD panel (P-reading) and at a standard distance. The standard distance will be comparable to the distance between the SP and the LCD panel (SP reading). To verify the calibrations follow the steps below:

- Turn the Lux meter ON;
- Press the RANGE button to switch the range to 0.00;
- Hold the lux meter at the surface of the LCD panel (P reading);
- Record the results in the “Results” field in ISIS;
- Press the RANGE button to switch the range to .000;
- Hold the light meter at the SP mark (SP reading); and
- Record the results in the “Comment” field in ISIS.

The light meter will continue to take readings. As readings are taken, the results are displayed on the digital readout. Take measurements at the following levels:

Luminance Level	Luminance (cd/m <sup>2</sup> )	Calibration Requirements	
		P reading	SP reading
Medium-low	85	0.79 – 0.90	> 0.009
Medium-high	439	4.13 – 4.65	> 0.056
Medium	193	1.81 – 2.04	> 0.023
Low	4.3	0.40 – 0.46	> 0.004
High	1000	9.40 – 10.60	> 0.141
Background	1.6	0.15 – 0.17	> 0.002

### Data Entry Screen for QC Checks

Complete all daily checks. Check “Done” for each item on the daily checks when complete. Enter the P readings in the “Result” field and the SP readings in the “Comment” field. If the readings are outside the acceptable calibration requirements, repeat the steps listed above. If the readings continue to fall outside the acceptable range, report this to the Westat component specialist and submit an UFO.

QC Check	Done	Result	Comment
Luminance at intermediate low level	<input checked="" type="checkbox"/>	0.80	0.010
Luminance at intermediate high level	<input checked="" type="checkbox"/>	4.29	0.060
Luminance at medium level	<input checked="" type="checkbox"/>	1.84	0.025
Luminance at low level	<input checked="" type="checkbox"/>	0.41	0.005
Luminance at high level	<input checked="" type="checkbox"/>	10.00	0.150
Luminance at the background level	<input checked="" type="checkbox"/>	0.16	0.002

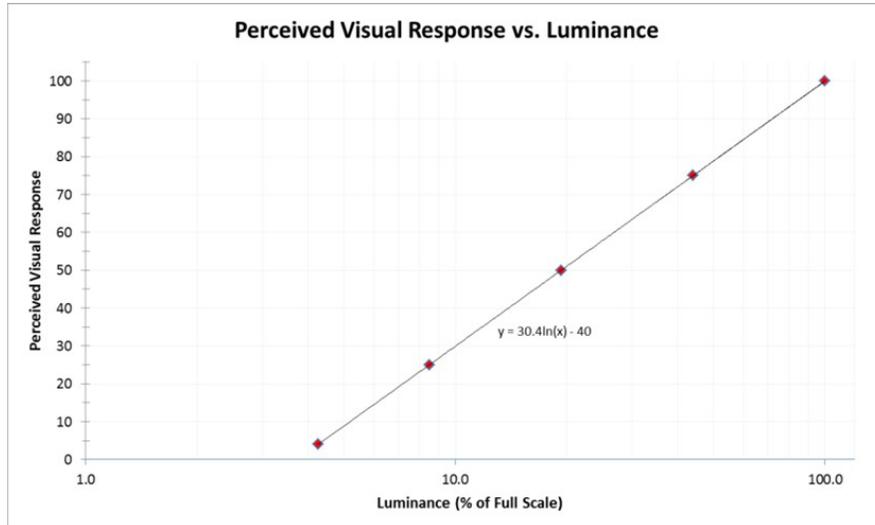
APPENDIX E

LUMINANCE PANEL

## APPENDIX E. LUMINANCE PANEL

### Perceived Visual Response (PVR) levels versus Luminance

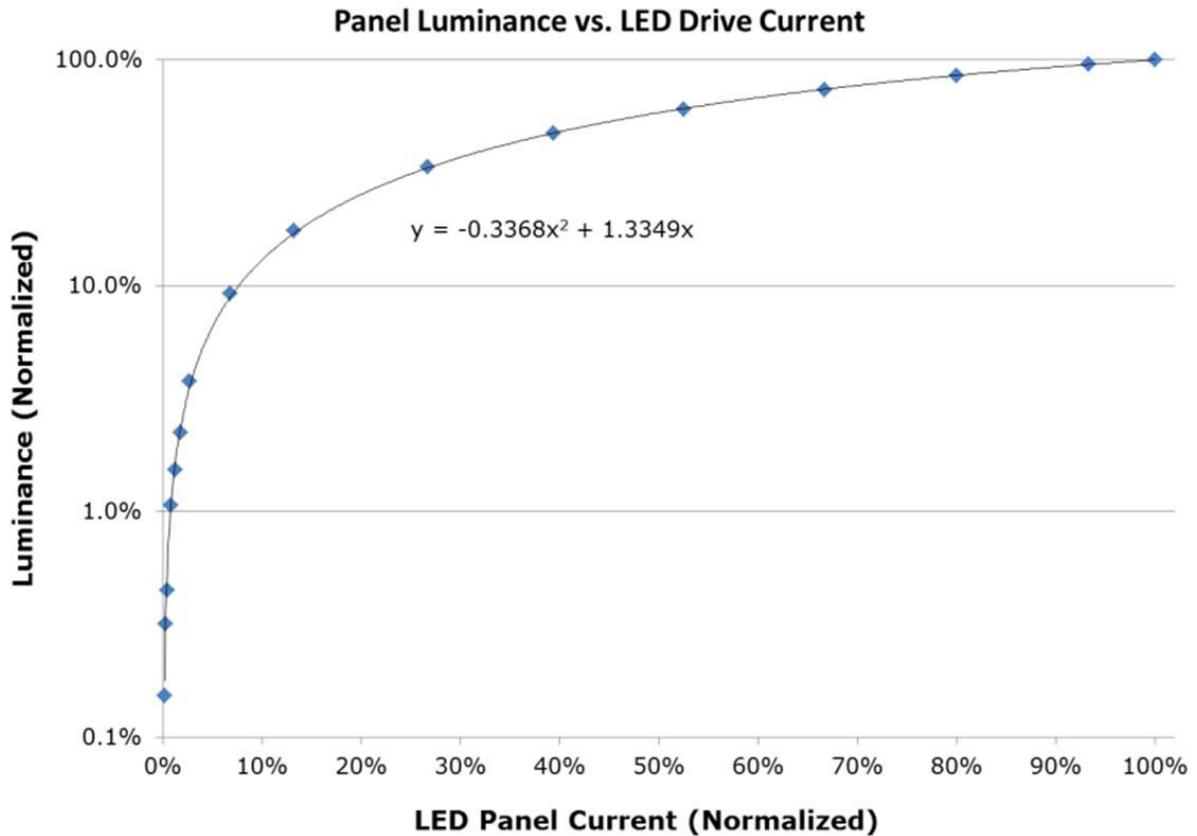
The five (5) target luminance values are specified below.



	Setting Number	PVR (% of Full Scale)	Actual Panel Luminance (cd/m <sup>2</sup> )
High (Full Scale)	5	100%	1000
High Intermediate	4	75%	439
Medium	3	50%	193
Low Intermediate	2	25%	85
Low	1	4%	4.3
Background	0	2%	3.8

A 12"x12" panel was characterized using a calibrated photometer located on the surface, and in the center, of the LED panel. Power from a precision adjustable constant current supply was used to drive the panel and determine the relative luminance emanating at the surface. Data was taken down to a level for which luminance values had a stability level better than 90 percent (less than 10% flicker). These results are graphed below.

## APPENDIX E. LUMINANCE PANEL

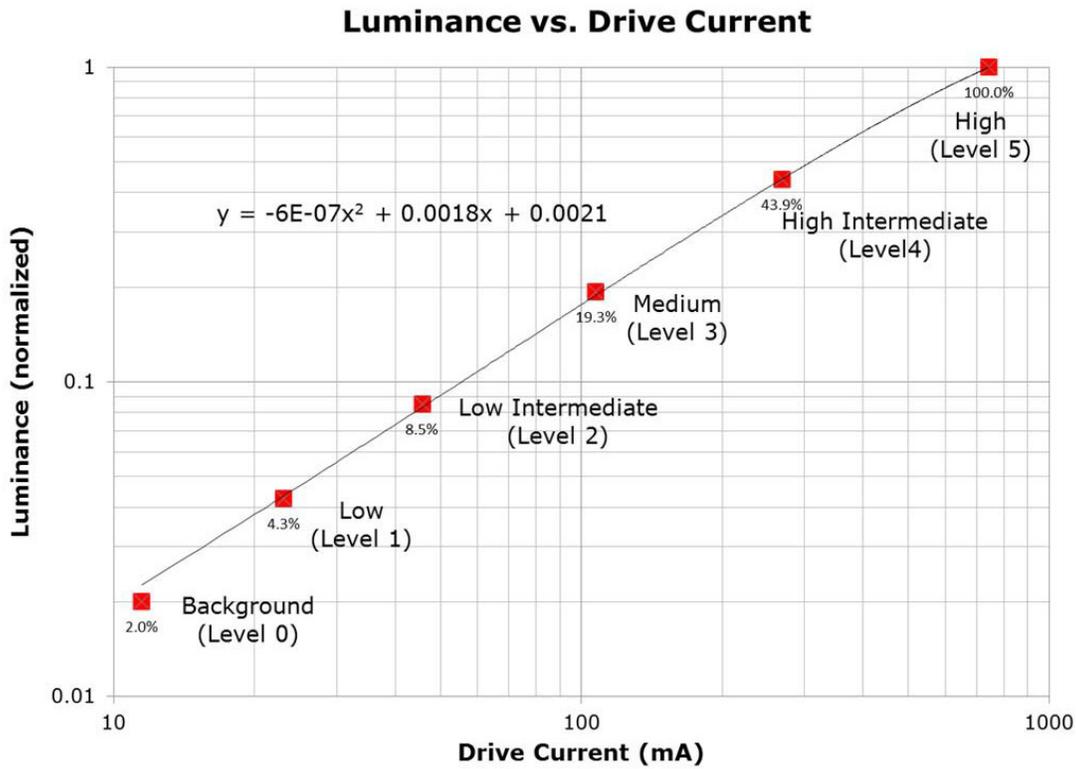


As can be seen, the panel can be run with dynamic range over two log, and still maintain reasonable stability and uniformity. The lowest stable setting observed has a luminance value of approximately 0.2% of the full scale value. This level is detectable by the examinee if it is a darkened environment (no overhead lights).

These results suggest that a background reference level could be developed such that all other test levels would be above this background level. A 2 percent panel luminance was chosen as sufficient for the background level.

Using these test results, the required current levels are then calculated and graphed below.

## APPENDIX E. LUMINANCE PANEL



Desired Luminance (% of Full Scale)	Calculated Current (mA)
100.0%	745.6
43.9%	268.8
19.3%	107.5
8.5%	45.8
4.3%	23.2
2.0%	11.5

As can be seen, the precision current controller must cover the range from about 10mA to 750mA with high levels of stability at each setting. To accomplish this task multiple current control sources are used, each developed to be operating at its optimal regulation point. When the examiner selects one of the above settings, the appropriate current source will be connected to the panel, and the approximate current shown above will be sent to the panel in a regulated manner. The precise current for each channel will be adjusted at the time of manufacture to ensure that the desired luminance shown above is provided.

**APPENDIX E. LUMINANCE PANEL**

**PANEL CALIBRATION**

**Model: 30646-01**  
S/N: 01031201

	<b>Setting Number</b>	<b>UDT Output</b>	<b>Percentage Output</b>
Low Intermediate	1	134.4	8.1%
High Intermediate	2	712.1	42.8%
Medium	3	306.6	18.4%
Low	4	67.73	4.1%
High (Full Scale)	5	1663	100.0%
Background		27.39	1.6%

**Model: 30646-01**  
S/N: 01031202

	<b>Setting Number</b>	<b>UDT Output</b>	<b>Percentage Output</b>
Low Intermediate	1	128.3	8.3%
High Intermediate	2	663.5	42.7%
Medium	3	286.4	18.4%
Low	4	63.6	4.1%
High (Full Scale)	5	1555	100.0%
Background		26.03	1.7%

**Model: 30646-01**  
S/N: 01031203

	<b>Setting Number</b>	<b>UDT Output</b>	<b>Percentage Output</b>
Low Intermediate	1	124.9	8.1%
High Intermediate	2	657.6	42.7%
Medium	3	283.1	18.4%
Low	4	62.6	4.1%
High (Full Scale)	5	1540	100.0%
Background		25.38	1.6%

**Model: 30649-01**  
S/N: 010051013

	<b>Setting Number</b>	<b>UDT Output</b>	<b>Percentage Output</b>
Low Intermediate	1	135	8.1%
High Intermediate	2	713.2	42.8%
Medium	3	306.7	18.4%
Low	4	67.61	4.1%
High (Full Scale)	5	1667	100.0%
Background		27.45	1.6%