



Laboratory Procedure Manual

Analyte: **Soluble Transferrin Receptor**

Matrix: **Serum**

Method: **Roche Tina-quant®**

Method No: 4042.03

Revised:

as performed by:

Nutritional Biomarkers Branch (NBB)
Division of Laboratory Sciences
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Important Information for Users

CDC periodically refines these laboratory methods. It is the responsibility of the user to contact the person listed on the title page of each write-up before using the analytical method to find out whether any changes have been made and what revisions, if any, have been incorporated.

**Soluble Transferrin Receptor in Serum
NHANES 2009-2010**

Public Release Data Set Information

This document details the Lab Protocol for testing the items listed in the following table:

Data File Name	Variable Name	SAS Label
TFR_F	LBXTFR	Transferrin receptor

1. Summary of Test Principle and Clinical Relevance

The method principle for measurement of soluble transferrin receptor (sTfR) is immuno-turbidimetry using Roche kits on the Hitachi Mod P clinical analyzer. Latex bound anti-sTfR antibodies react with the antigen in the sample to form an antigen/antibody complex. Following agglutination, this is measured turbidimetrically.

The transferrin receptor is an integral membrane glycoprotein having a molecular weight of 190 kilodaltons (kD). It consists of two identical subunits linked by disulfide bridges. Each of the monomers has an 85 kD C-terminal component which can bind an iron-laden transferrin molecule. Proteolysis leads to the soluble form of the transferrin receptor. In plasma, sTfR is present in the form of a complex with transferrin having a molecular weight of approximately 320 kD. The serum concentration of sTfR is directly proportional to the concentration of the receptor on the membrane.

The uptake of iron by the body's cells is controlled by expression of the transferrin receptor (TfR). If the intracellular iron stores are exhausted - corresponding to a ferritin concentration of less than 12 ug/L - then more TfR is expressed. The affinity of the transferrin receptor to transferrin depends on the latter's loading state. As 80-95% of the transferrin receptor molecules are localized on erythropoietic cells, the TfR concentration (and hence also the sTfR concentration) reflects the iron requirement of the cells. When iron deficiency exists, the sTfR concentration in serum rises even before the hemoglobin concentration is significantly depressed. The sTfR concentration reflects the iron storage status. A precise assessment of the iron status can be obtained by determining the sTfR index (sTfR concentration/log ferritin concentration).

As - in contrast to ferritin - the concentration of sTfR is not affected by acute phase reactions, such as acute liver function disorders or malignant tumors, it is possible to differentiate between anemia of chronic disease (ACD) and iron deficiency anemia (IDA). Elevated sTfR values are also found in polycythemia, hemolytic anemia, thalassemia, hereditary spherocytosis and vitamin B12 deficiency. Elevated sTfR concentrations occur during pregnancy when there is a deficiency of functional iron. Therapy with rhEPO can be monitored via the sTfR concentration.

2. Safety Precautions

Consider all plasma specimens potentially positive for infectious agents including HIV and the hepatitis B virus. We recommend the hepatitis B vaccination series for all analysts working with whole blood and/or plasma. Observe universal precautions; wear protective gloves, laboratory coats, and safety glasses during all steps of this method. Discard any residual sample material by autoclaving after analysis is completed. Place disposable plastic, glass, and paper (pipet tips, autosampler vials, gloves, etc.) that contact plasma in a biohazard autoclave bag and keep these bags in appropriate containers until sealed and autoclaved. Wipe down all work surfaces with 10% bleach solution when work is finished.

Handle acids and bases with extreme care; they are caustic and toxic. Handle organic solvents only in a well-ventilated area or, as required, under a chemical fume hood.

Reagents and solvents used in this study include those listed in Section 6. Material safety data sheets (MSDSs) for these chemicals are readily accessible as hard copies in the lab. If needed, MSDS for other chemicals can be viewed at the ILPI MSDS website.

3. Computerization; Data System Management

Calculation of sTfR values are accomplished with the software on the Hitachi Mod P instrument. Generated data is copied onto a floppy disk and archived to My Network Places:
\\cdc\project\CCEHIP_NCEH_DLS_NBB_LABS\Instrument Results\Hitachi Mod PE\MOD PE
Serum: as an ASCII file. Transmission of data from A: to the Microsoft Access Network Database is described below:

Step 1 – Analyst – Import data file into FrontEnds:

Double click the FrontEnds icon on desktop, password entry required
[Add Sample Results to Database] (under Batch & X-Batch)
[Import Instrument Data File] - Enter information (instrument, assay, analyst, study)
[Import] – In “select data file” window, choose A: and import file number assigned for the date/run number. Check that sample ID's are recognized
[Transfer]

Step 2 – Analyst – Review run in FrontEnds:

[Run Review] (under Batch & X-Batch) – Select assay
[Show runs] – Cursor to desired run, enter sample set name and comments
[QC Results] – Review QC results for transmission errors and whether they pass the 2S limits
[Print Report] [Back]
[Sample Results] – Review patient results to assure proper information transmission, enter appropriate comment codes on flagged samples
[Set Final] results that are ready to be reported
[Set Reviewed]
[Print Report] [Back]

Step 3 – Analyst – Send email and run folder to QA Officer:

An e-mail is sent to the QA Officer including the following run information: Analysis date, Instrument, Study, Groups, File name, Batch ID, Run #, and QC Status. Noteworthy comments are included in the email. All printouts including raw data are submitted in a run folder to the QA Officer who reviews the Bench QC data via the FrontEnds database as described below.

Step 4 – QA Officer – Review Bench QC via FrontEnds:

Double click the FrontEnds icon on desktop, password entry required
[Export QC to SAS] (under Batch & X-Batch) – Select Assay, Date range and Controls
[Make QC Data Infile] – Save file to I: appropriate subfolder for archival
[Run SAS] – SAS will automatically open, [go], review each generated plot, print QC cover page and standard deviation plot, [Back]
[Run Review] (under Batch & X-Batch) – Select assay
[Show runs]
[Sample Results]
[Set Batch QC] – accept or reject
[Set Reviewed]
Forward email from Analyst to Team leader reviewer (for Blind QC review) specifying Bench QC status of the run.

Step 5 – Team leader – Review Blind QC and other parameters and set results ready in FrontEnds:

Double click the FrontEnds icon on desktop.

[Run Review] (under Batch & X-Batch) – Select assay, then desired run

[Blind QC Results] – Review whether Blind QC results pass the 2S limits

[Print Report] [Back]

Check other parameters if applicable (i.e., background, calibration curve, repeat values, replicates, signal intensity)

[Set RQC] – accept or reject

Verify that appropriate comment codes have been applied, that final values have been set correctly and that repeat results are as expected

[Set Ready] – Final results will be set ready to be exported

[Set Reviewed]

Forward email from QA Officer to Supervisor specifying that results can be exported; include any relevant comments.

Step 6 – Supervisor – Approvals and Export of Results via FrontEnds:

Double click the FrontEnds icon on desktop, password entry required

[Run Review] (under Batch & X-Batch) – Select assay, then desired run

Perform a final review

[Set Reviewed]

[Export/Report Results] (under Study Functions) – Select study, select analytes/panel, use selected panel

[Generate Pre-Export Text File] – Review file on

\\cdc\project\CCEHIP_NCEH_DLS_NBB_OC\QA\Data handling\To be transmitted

[Generate Export Text File and Set Results Exported] –

\\cdc\project\CCEHIP_NCEH_DLS_NBB_OC\QA\Data handling\To be transmitted

FTP file to Westat

Send Westat an email that file was transmitted

Move transmittal file from \\cdc\project\CCEHIP_NCEH_DLS_NBB_OC\QA\Data handling\To be transmitted to \\cdc\project\CCEHIP_NCEH_DLS_NBB_OC\QA\Data handling\Transmitted\Appropriate Year Folder.

For NHANES, data is transmitted electronically weekly to Westat's ISIS computer system and transferred from there to NCHS. Abnormal values are confirmed by the analyst, and codes for missing data are entered by the analyst and are transmitted as part of the data file to the Westat ISIS computer, and are eventually forwarded to NCHS. Westat also prepares the abnormal report notifications for the NCHS Survey Physician.

Files stored on the network or CDC mainframe are automatically backed up nightly by DLS LAN support staff and CDC Data Center staff, respectively. Backup of the daily data containing all raw data files and result files for each run are the responsibility of the analyst. Typically these files are backed up regularly onto a floppy disk or a CD-ROM using a CD writer.

Documentation for data system maintenance is contained in printed copies of data records, as well as in "system log" files on the local hard drives used for the archival of data.

4. Specimen Collection, Storage, and Handling Procedures; Criteria for Specimen Rejection

- a. Use serum or plasma collected by standard venipuncture technique. Lithium and sodium heparin plasma may be used.
- b. Centrifuge samples containing precipitate before performing the assay.
- c. A 500- μ L sample of serum/plasma is preferable to allow for repeat analyses; a volume of 150 μ L is required for the sample cup.
- d. The appropriate amount of serum/plasma is dispensed into a Nalge cryovial or other plastic screw-capped vial labeled with the participant's ID.
- e. Specimens collected in the field are frozen, and then shipped on dry ice by overnight mail. Frozen samples are stored at -70°C . Samples are stable for up to 2 weeks at $2-8^{\circ}\text{C}$ or 4 weeks if stored at $\leq -20^{\circ}\text{C}$. Multiple freeze/thaw cycles are generally not recommended, however samples can withstand up to 3 freeze/thaw cycles.
- f. Ensure patient samples, calibrators and QC are at ambient temperature ($20-25^{\circ}\text{C}$) before measurement.
- g. Because of possible evaporation effects, all samples, calibrators, and QC on the analyzer should be measured within 2 hours.
- h. Specimen handling conditions are outlined in the Policies and Procedures Manual of DLS (copies are available in the Nutritional Laboratory and the electronic copy of this file is located at \\cdc\project\CCEHIP_NCEH_DLS_NBB_LABS\CLIA\DLS Policies and Procedures Manual). The protocol discusses collection and transport of specimens and the special equipment required. In general, plasma should be transported and stored at no more than -20°C . Samples thawed and refrozen less than twice are not compromised. If there is more than one analyte of interest in the specimen and it needs to be divided, the appropriate amount of blood or plasma should be transferred into a sterile Nalge cryovial labeled with the participant's ID.

5. Procedures for Microscopic Examinations; Criteria for Rejection of Inadequately Prepared Slides

Not applicable for this procedure

6. Preparation of Reagents, Calibration (Standards), Controls, and All Other Materials; Equipment and Instrumentation

a. Reagent Preparation

All reagents are supplied by Roche Diagnostics in liquid form ready to be used. If the entire reagent kit is not used in one run, store the kit at $2-8^{\circ}\text{C}$ on the analyzer until the expiration date of the reagent is reached or the reagent has been on the analyzer for 90 days, whichever comes first?

b. Standards Preparation

0.9% NaCl is used as the zero standard and PreciSet sTfR, supplied by Roche Diagnostics, includes 5 standards in liquid form with concentrations varying between calibrator kit lot numbers. The standard concentrations need to be installed on the instrument before using. Store the standards at $2-8^{\circ}\text{C}$ until the expiration date of the kit.

c. Preparation of Quality Control Materials

1) Roche QC pools:

Commercially prepared quality control material can be purchased from Roche Diagnostics in two levels (sTfR Control I and sTfR Control II). Controls are in liquid form and ready to use. Unopened controls are stable at 2-8°C until expiration date. Once opened, controls are stable for 4 weeks at 2-8°C. Controls should be allowed to come to room temperature before analyzing. Control values are lot specific and values for each new lot should be entered into the Hitachi Mod P[®] before analyzing a new lot number of control.

2) CDC QC pools:

Low, medium and high serum based QC pools are prepared and characterized in-house. Means plus range limits for all pools are established by analyzing duplicates for at least 20 consecutive runs.

The low QC pool is prepared by selecting and pooling serum that contains low levels of sTfR (~2-3 mg/L) to represent a sample with normal sTfR concentration.

The high QC pool is prepared by selecting and pooling serum that contains elevated levels of sTfR (~5-7 mg/L) to represent a sample with iron deficiency.

d. Other Materials

The following materials are all provided by the manufacturer (Roche Diagnostics):

- 1) Sample trays
- 2) Sample cups (standard and micro)
- 3) Reaction Cells
- 4) Wash solutions (basic wash, cell wash)
- 5) Hitergent
- 6) Lamp
- 7) Diluent
- 8) System Cleaning Solution
- 9) PreciSet sTfR Calibrators (2-6) and Controls (sTfR 1 and sTfR 2)

e. Instrumentation

- 1) Roche Diagnostics Hitachi Mod P[®] system (Roche Diagnostics, Indianapolis, IN)
- 2) Daigger Vortex Genie 2 (VWR, Suwanee, GA)
- 3) Eppendorf micropipet and tips (Brinkmann Instruments Co., Westbury, NY)

7. Calibration and Calibration Verification Procedures

The reagents are stable for 90 days on the analyzer or until the expiration date on the reagent bottle is reached, whichever comes first.

Calibration can be manually programmed on the Calibration Status screen or calibration can be requested via the graphical icon representing the system in the status line. If the Calibration button is yellow, click on it to display the Calibration and QC Select window. Touch the yellow "Recommended" button in the Calibration area to select the recommended calibration. Load the required calibrators in the pre-assigned calibration racks (black) and controls in the pre-assigned QC rack (white). Press the "Start" global button and then press "Start" on the Start Conditions screen.

***Verify that the calibration and QC results are valid
before measuring routine samples.***

The Hitachi Mod P[®] system must be recalibrated if any of the following events occur:

A new lot of reagent is started.

One or more QCs are out of specification.

Any dispense system component is replaced or any major maintenance is performed on the instrument to include replacing the lamp.

Cells are replaced.

A CALIB error occurs indicating a difference in current values from previously stored values of >20%. Check QC and if in control no recalibration is necessary.

A STD? SENS? or CALERR flag. Error codes let you know what aspect of calibration failed. Errors should be investigated and corrected and calibration repeated.

NIBSC reference reagent 07/202, recombinant soluble transferrin receptor, was released in 2009 with an assigned value of 21.7 mg/L or 303 nmol/L (when reconstituted with 0.50 mL distilled or deionised water). These values apply to free sTfR monomer. The Roche assay measures 60 mg/L for this material.

There is no external proficiency testing program available for sTfR. CDC is performing in-house proficiency testing at least twice a year.

8. Procedure Operating Instructions; Calculations; Interpretation of Results

a. Preliminaries

- 1) Allow frozen serum/plasma (patient samples), calibrators and QC to reach ambient temperature.
- 2) Perform the required maintenance on the Mod P[®] system (monthly, weekly, and daily).
- 3) Make sure the analyzer and the test required is not masked.
- 4) If you will be running the same tests on all samples, go to the "Start" global button and set the default profile.
- 5) After backing up the data go to the Data Review screen and clear all data from the previous day. This must be done in order to reuse the same barcoded tubes.

b. Preparing the Run

One run is defined as 100 samples or less (including calibrators and controls). Controls are run at the beginning and the end of each run.

Each run must contain three levels (low, medium and high) of CDC sTfR QC pools at the beginning of the run before patient samples are run and at the end of the designate run.

When performing small runs or confirmation (repeat) runs, all levels of CDC sTfR QC pools must be run in duplicate.

NOTE: Be sure to backup all previous test results and clear the “data review” screen before starting a new run.

- 1) Before running samples, ensure that no air bubbles are present in the sample cups. Break a wood applicator into pieces and use them to pop the bubbles if necessary.
- 2) For a calibration run: Pipet 150 µL of calibrator into sample cups and place in their pre-assigned positions in **black** calibrator racks. Place loaded racks on the input buffer tray.
- 3) To run QC: Pipette 150 µL of each nonbarcoded QC into a sample cup and place atop the 13 x 75 tube in the pre-assigned control position of the **white** QC racks. Place loaded racks on the input buffer tray.
- 4) To run samples: Place empty sample cups onto barcode labeled 13 X 75 tubes in **gray** sample racks and pipette 150 µL of the serum samples into the sample cup. Pipette 20-25 samples at a time.
- 5) Ensure that the amount of reagents, diluent, and wash solutions are adequate for the amount of samples to be run. You may place more than one bottle of reagent at a time on the analyzer however; avoid using more than one lot number of reagent for a single run.

c. Initiating a Run

NOTE: Do not load samples on the input tray if the green light is flashing.

When the instrument starts, it will run the default profile on all samples unless programmed differently prior to loading.

- 1) Once you have loaded racks onto the sample input buffer, click on the “Start” global button.
- 2) Click “Start” on the Start Conditions screen that appears. This will start the instrument.
- 3) After the tube barcode is scanned, go to the “Workplace” screen and select the “data review” tab.
- 4) To enter the patient ID, highlight the line that contains the scanned tube number. Click the “demographics” button at the bottom of the screen.
- 5) Place the cursor in the patient ID box and scan in the barcode from the patient vial that corresponds to the tube number the sample was placed in.
- 6) Click “OK” and continue until all patient ID’s are entered.
- 7) Step 6 must be completed prior to printing results and backing up data.

d. End of Assay

- 1) Once results are complete, review all results from the "Data Review" screen.
- 2) Highlight all results to be printed and click the "print" global button.
- 3) Check "both" to print original result and all repeats. Click "print" to print the data.
- 4) To backup the data, insert 3 ½ inch disk into A:\ drive and highlight all samples to archive on the "data review" screen,
- 5) Click "Backup data" on the bottom of the screen. A box will appear asking how you want to save the data (Floppy or Zip, ASCII or binary) and what the file name is.
- 6) First, save the file to the floppy as an ASCII file and use the date the run was done as the file name.
- 7) Next, save the file to the zip drive as a binary file and use the date the run was done as the file name.
- 8) After all data is backed up, "delete all" data from the "data review" screen.

e. System Maintenance

The system maintenance (refer to the Modular Analytic Operator's Manual) consists of daily, weekly, and monthly maintenance [13].

- 1) Daily maintenance should be performed at the start of each 8-hour shift, or more frequently, if necessary. It consists of an incubation bath water exchange, probe wash and clean, and photometer check, cleaning and adjusting stirrers and probes and checking the printer paper supply. Reagent, wash, diluent volumes and reagent compartment temperatures should be checked before running samples. At the end of the day, the "green rack" should be run to clean probes and condition the electrodes.
- 2) Weekly maintenance consists of performing a cell wash and cell blank.
- 3) Monthly maintenance consists of cleaning the water bath and filter, flushing the rinse stations, cleaning the reagent disk compartment and cleaning the drain ports. Since we do not utilize the analyzer on a daily basis, the reaction cells and lamp are replaced every 2 months rather than monthly as recommended.

f. Special Method Notes

The system can be completely turned off over the weekend or extended holidays, when you will be taking the instrument apart, or when indicated by maintenance procedure or error code.

g. Calculations

All calculations are performed by the Hitachi Mod P[®] Software system using a machine-stored calibration curve.

h. CDC modifications

The method is run exactly as stipulated by Roche Diagnostics; CDC has introduced no modifications.

9. Reportable Range of Results

The maximum reportable range is dependent on the concentration of the highest standard. For the purposes of CDC reporting, we will use a reportable range of 0.5-40 mg/L. Samples with values >5.5 mg/L are automatically reanalyzed using routine (normal) sample volume. Samples diluted via automatic rerun have an extended reportable range of 0.5-80 mg/L.

10. Quality Control (QC) Procedures

a. Blind Quality Control

Blind QC specimens are inserted prior to the arrival of the samples in the Nutritional Biomarkers Branch. These specimens are prepared at two levels so as to emulate the patient samples; the labels used are identical to those used for patient samples. One blind QC specimen randomly selected for concentration is included at a randomly selected location in every 20 specimens analyzed.

b. Bench Quality Controls

Bench QC specimens are prepared from three serum pools, which represent low, medium and high levels of sTfR in serum. These pools are prepared in the same manner as patient samples and analyzed in duplicate as part of each run.

The results from the pools are checked after each run. The system is declared "in control" if both QC results are within 2s limits and the run is accepted. If one of the three QC results is outside the 2s limits then apply rules below and reject if any condition is met - the run is then declared "out of control":

1_{3s} Any of the three QC results is outside the 3s limit

2_{2s} Two QC results in the run are outside the 2s limit (same side of mean)

R_{4s} Sequential QC results (either within the run or across runs) are outside the 2s limit on the opposite sides of the mean

10_x Ten sequential QC results (across pools and across runs) are on the same side of the mean.

A QC program written in SAS is available from the DLS Quality Assurance Officer and should be used to apply these rules to QC data and generate Shewhart QC charts. No results for a given analyte are to be reported from an analytical run that has been declared "out of control" for that analyte as assessed by internal (bench) QC.

The initial limits are established by analyzing pool material in 20 consecutive runs and then reevaluated quarterly. When necessary, limits are updated to include more runs.

While a study is in progress, QC results are stored in the ACCESS database. For runs that are not imported into ACCESS (exception, research-type runs), QC results are stored electronically in the analyte-specific folder on \\cdc\project\CCEHIP_NCEH_DLS_NBB_LABS\Data handling\QC\Hitachi MOD PE QC. A hardcopy of the QC results from each run is also kept by the analyst.

11. Remedial Action if Calibration or QC Systems Fail to Meet Acceptable Criteria

Check to make sure that the hardware is functioning properly.

Recalibrate the instrument.

If the steps outlined above do not result in correction of the "out of control" values for QC materials, consult the supervisor for other appropriate corrective actions.

Do not report analytical results for runs not in statistical control.

12. Limitations of Method; Interfering Substances and Conditions

Only one freeze/thaw cycle is recommended. Samples containing particulate matter should be centrifuged and the material removed before analysis. Results are not known to be affected by icteric, hemolyzed or lipemic specimens.

13. Reference Ranges (Normal Values)

sTfR reference ranges are assay-specific. The expected values are 2.2-5.0 mg/L for men and 1.9-4.4 mg/L for women [14]. Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

14. Critical Call Results ("Panic Values")

The collaborating agency with access to patient identifiers or the responsible medical officer is notified by email or FAX by the supervisor of any sTfR result that is >5.5 mg/L, which possibly represents iron deficiency. Copies of FAXes sent concerning abnormal results are kept in a notebook by the supervisor for the duration of the study. For NHANES 1999+, since data are transmitted several times weekly to the Westat ISIS computer, Westat automatically notifies the NCHS survey physician.

15. Specimen Storage and Handling during Testing

Specimens are allowed to reach room temperature during preparation. The unused portion of the patient specimen is returned to the freezer.

16. Alternate Methods for Performing Test of Storing Specimens if Test System Fails

If the analytical system fails, we recommend that the specimens be stored at -20°C until the analytical system is restored to functionality.

17. Test Result Reporting System; Protocol for Reporting Critical Calls (If Applicable)

The collaborating agency with access to patient identifiers or the responsible medical officer is notified by email or FAX by the supervisor of any sTfR result that is >5.5 mg/L, which possibly represents iron deficiency. Copies of FAXes sent concerning abnormal results are kept in a notebook by the supervisor for the duration of the study.

Test results that are not abnormal are reported to the collaborating agency at a frequency and by a method determined by the study coordinator. Generally, data from this analysis are compiled with results from other analyses and sent to the responsible person at the collaborating agency as an ASCII text file, either through electronic mail or on a diskette.

For NHANES 1999+, all data are reported electronically weekly to the Westat ISIS computer and then are transferred to NCHS. For some smaller studies, hard copies of a data report are sent, as well as the results in electronic format.

18. Transfer or Referral of Specimens; Procedures for Specimen Accountability and Tracking

The Microsoft Access database is used to keep records and track specimens for NHANES 1999+. If sTfR analysis is done for smaller, non-NHANES studies, records are kept on files in \\cdc\project\CCEHIP_NCEH_DLS_NBB_LABS\ on the DLS LAN.

We recommend that records, including related QA/QC data, be maintained for 10 years after completion of the NHANES study. Only numerical identifiers should be used (e.g., case ID numbers). All personal identifiers should be available only to the medical supervisor or project coordinator. Residual serum from these analyses for non-NHANES studies may be discarded at the request of the principal investigator, or may be transferred to the CDC CASPIR facility for use by other investigators. Very little residual material will be available after NHANES analyses are completed, and these vials may be routinely autoclaved.

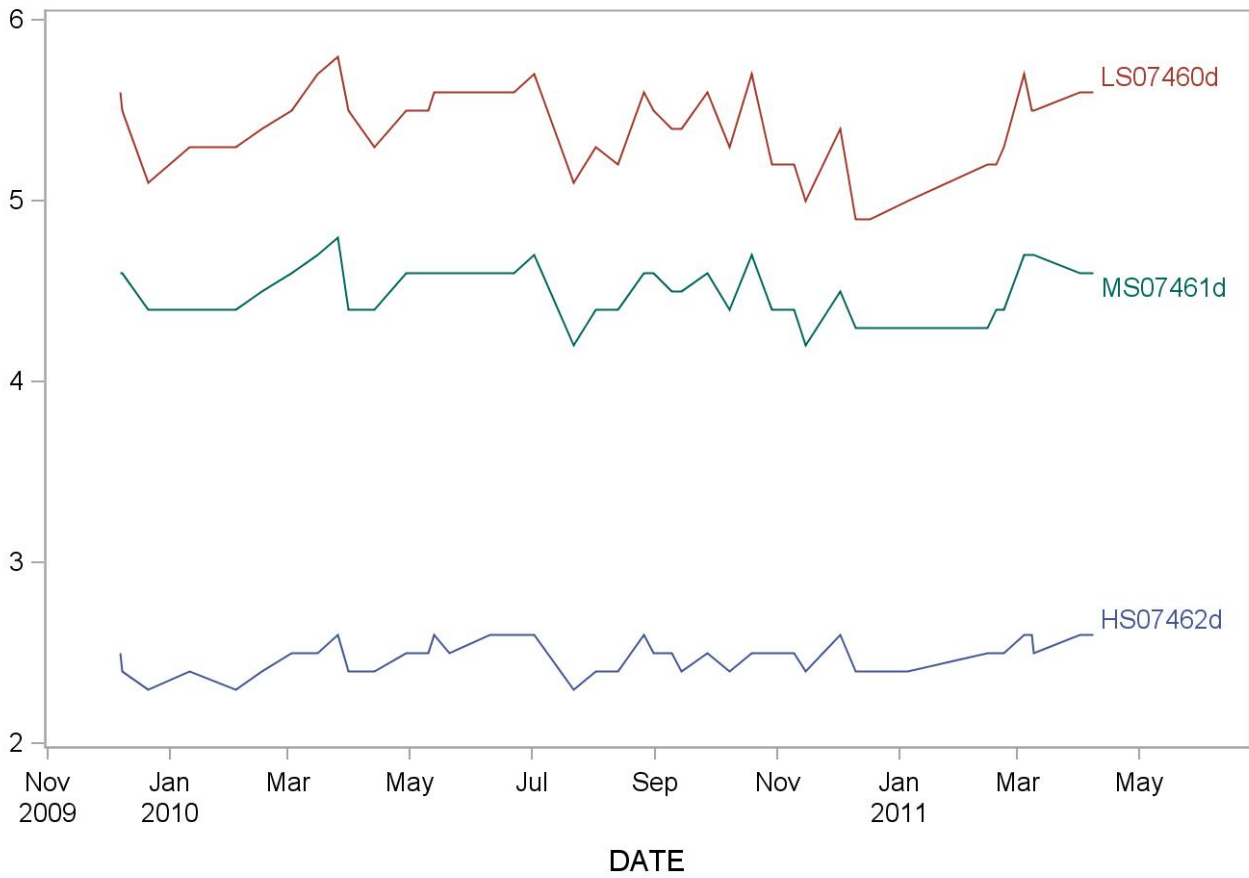
The exact procedure used to track specimens varies with each study and is specified in the study protocol or the interagency agreement for the study. Copies of these documents are kept by the supervisor. In general, when specimens are received, the specimen ID number is entered into a database and the specimens stored in a freezer at -70°C. The specimen ID is read off of the vial by a barcode reader attached to the computer used to prepare the electronic specimen table for the analytical system. When the analyses are completed, the DIF file containing the electronic copy of the results is loaded into the database, and the analytical results are linked to the database by ID number. The analyst is responsible for keeping a notebook containing the ID numbers of specimens prepared incorrectly, those with labeling problems, and those with abnormal results, together with information about these discrepancies.

19. Summary Statistics and QC Graphs

Summary Statistics for Transferrin Receptor (mg/L)

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
HS07462d	71	07DEC09	08APR11	2.44	0.11	4.4
LS07460d	77	07DEC09	08APR11	5.33	0.23	4.3
MS07461d	83	07DEC09	08APR11	4.44	0.16	3.6

2009-2010 Transferrin Receptor (mg/L) Quality Control



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Appendix (Addendum 1)

Addendum 1

Ruggedness Testing

As this assay must be performed according to the manufacturer's specifications, none of the parameters can be altered. Therefore, ruggedness testing has not been done for this assay.