Laboratory Procedure Manual

Analyte: **Triiodothyronine (T3), Free**

Matrix: **Serum**

Method: **Roche Cobas 6000 (e601 module)**

As performed by: **University of Minnesota**
Advanced Research and Diagnostic Laboratory (ARDL)
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Important Information for Users

The Advanced Research and Diagnostic Laboratory (ARDL) periodically refine 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.

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
THYROD_K	LBXT3F	Triiodothyronine, Free (FT3) (pmol/L)

1. SUMMARY OF TEST PRINCIPLE AND CLINICAL RELEVANCE

Triiodothyronine is one of the thyroid hormones present in serum which regulates metabolism. Determination of this hormone concentration is important for the diagnostic differentiation of euthyroid, hyperthyroid, and hypothyroid states. The major fraction of total triiodothyronine is bound to the transport proteins (TBG, prealbumin, albumin). Free triiodothyronine (FT3) is the physiologically active form of the thyroid hormone triiodothyronine (T3). The determination of free T3 has the advantage of being independent of changes in the concentrations and binding properties of the binding proteins; additional determination of a binding parameter (T-uptake, TBG) is therefore unnecessary.

This assay uses a competition principle. 15 µL of sample and an anti-T3-specific antibody labeled with a ruthenium complex are incubated together. After addition of biotinylated T3 and streptavidin-coated microparticles, the still-free binding sites of the labeled antibody become occupied, with formation of an antibody-hapten complex. The entire complex is bound to the solid phase via interaction of biotin and streptavidin. The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell/ProCell M. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.

Cobas e601 Application Code: 195

2. SAFETY PRECAUTIONS

Caution: This product is of human and animal origin. Handle as though capable of transmitting infectious disease. Wear appropriate PPE when handling equipment, reagents, and samples.

3. COMPUTERIZATION; DATA SYSTEM MANAGEMENT

ARDL utilizes a highly specialized Laboratory Information System (LIS) (STARLIMS, Abbott Informatics Corporation; Hollywood, FL, 33021-6755) for all lab functions. Major instrument platforms are interfaced directly to the LIS, allowing data to be electronically transferred directly to the main database. The system provides an extensive quality

assurance package and data management tools. Numerous networked computer workstations are used in the laboratory for data management and transmission, and also include software for word and spreadsheet creation and manipulation, statistical analysis, report presentation, and electronic communication. All workstations are user password protected with job specific security access levels and have idle time out functionality. All systems are redundantly backed up on a real time basis.

4. **SPECIMEN COLLECTION, STORAGE, AND HANDLING PROCEDURES; CRITERIA FOR SPECIMEN REJECTION**

a. **Specimen Type and Requirements:** Use serum that has been separated from the clot within one hour of collection. Serum or plasma (Li-heparin, K2-EDTA, and K3-EDTA) are acceptable. Serum and plasma are stable for seven days at 2-8ºC, one month at -20°C, and longer at –70ºC. Freeze only once. Specimens must be at room temperature (20-25 ºC) prior to assay. Specimens with visible particulates should be centrifuged for 10 minutes at 1500xg before use. This specimen is received frozen and the test is analyzed from NHANES Vial 118.

b. **Specimen Volume:** The required dead volume is 150uL when the specimen is stored in a 2-mL screw cap conical microvial (e.g. Sarstedt #72.664 or Fisher #0554166). Use of larger vials or round/flat-bottomed vials will increase the dead volume requirement. Test sample volume is 15 µL for serum or plasma.**Dead volume is not recoverable if sample is transferred into a sample cup.

c. **Acceptable Specimens/Unacceptable Specimens:** Serum or plasma (Li-heparin, K2- EDTA, and K3-EDTA) are acceptable. Other anticoagulants are not acceptable.

d. **Specimen Stability and Storage:** Separated serum or plasma should be removed from the cells within one hour of collection. Serum and plasma are stable for seven days at 2-8ºC, one month at -20°C, and longer at –70ºC. Freeze only once. Specimens must be at room temperature (20-25 ºC) prior to assay. Specimens with visible particulates should be centrifuged for 10 minutes at 1500xg before use.

e. **Interferences or limitations:**

- Icteric index < 66: no interference.

•Hemolytic index < 1000: no interference.

•Lipemic index < 2000: no interference.

•Biotin < 70 ng/mL: no interference. In patients receiving therapy with high biotin doses (i.e. > 5 mg/day), no sample should be taken until at least 8 hours after the last biotin administration.

•No interference was observed from rheumatoid factors up to a concentration of 1200 IU/mL.

•Any influence that might affect the binding behavior of the binding proteins can alter the result of the FT3 tests (e.g. drugs, NTIs (Non-Thyroid Illness) or patients suffering from FDH (Familial Dysalbuminemic Hyperthyroxinemia).

•In vitro tests were performed on 17 commonly used pharmaceuticals. No interference with the assay was found.

•In in vitro studies the drugs Furosemide and Levothyroxine caused elevated FT3 findings at the daily therapeutic dosage level.

•In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. These effects are minimized by suitable test design.

f. **Specimen Handling and Transport:** Mix specimens well, allow clot to fully form (if serum), and centrifuge 10 minutes at 2000 x g before use. Aliquot a minimum of 0.150 mL. Freeze sample until shipment. Ship frozen on dry ice.

5. PROCEDURES FOR MICROSCOPIC EXAMINATIONS; CRITERIA FOR REJECTION OF INADEQUATELY PREPARED SLIDES

Not applicable for this procedure.

6. EQUIPMENT AND INSTRUMENTATION, MATERIALS, REAGENT PREPARATION, CALIBRATORS (STANDARDS), AND CONTROLS

a. Reagents and Supplies

Roche product # 0647206 190, FT3 reagent kit (200 tests):

b. Reagent Preparation (*Reagents are ready to use; no preparation required)

•R1 reagent. Anti-T3-Ab~Ru(bpy) (gray cap), 1 bottle, 18 mL: Monoclonal anti-T3-antibody (sheep) labeled with ruthenium complex 18 ng/mL; phosphate buffer 100 mmol/L, pH 7.0; preservative.

•R2 reagent. T3~biotin (black cap), 1 bottle, 18 mL: Biotinylated T3 2.4 ng/mL; phosphate buffer 100 mmol/L, pH 7.0; preservative.

• M. Streptavidin-coated microparticles (transparent cap), 1 bottle, 12 mL: Streptavidin-coated microparticles 0.72 mg/mL; preservative.

•Storage and stability: Keep reagents stored at 2-8°C until use. Unopened, reagents are stable until the expiration date stated on the cassette. The reagents are stable at 2-8°C for 12 weeks once opened, and for 6 weeks refrigerated on the analyzer. Do not freeze. Store the Elecsys reagent kit upright in order to ensure complete availability of the microparticles during automatic mixing prior to use.

c. Equipment/Instrumentation-

Roche Cobas 6000 Chemistry Analyzer (Roche Diagnostics Corporation, Indianapolis, IN 46250)

•The Millipore Elix Gulfstream Clinical 35 System is designed to meet CLSI Clinical Laboratory Reagent Water (CLRW) standards. Water purification is achieved by reverse osmosis, electrodeionization, bactericidal 254 nm UV lamp and 0.22 µm filtration.

d. Specimens are run in singleton

e. Quality Control

- Roche PreciControl Universal: Ref. # 11731416 160. 4 x 3.0 mL for each level, PreciU1 and PreciU2. To prepare, carefully dissolve the contents of one bottle by adding exactly 3.0 mL of deionized water and allow to stand closed for 30 minutes to reconstitute. Mix carefully, avoiding foam formation. Transfer aliquots of the freshly reconstituted controls into empty labeled

ControlSet Vials. Attach the supplied labels to the additional bottles. Roche recommends performing only one control procedure per aliquot. The lyophilized controls are stable up to the stated expiration date. Aliquots intended for storage should be frozen immediately at -20 °C. Reconstituted control is stable for three months at -20°C (freeze only once) or at 2-8°C for 3 days. Store calibrators upright in order to prevent the calibrator solution from adhering to the snap-cap.

- Both levels of quality control are analyzed at the start of the day and results are verified for acceptability prior to testing specimens. Quality control is also analyzed at the end of the work day, with change in reagent, after major maintenance, or as needed for troubleshooting.

7. CALIBRATION AND CALIBRATION VERIFICATION PROCEDURES

Roche FT3 III Calset: Ref. # 06437222 190. 2 x 1.0 mL. A lyophilized human serum matrix with added T3 in two concentration ranges. The Calset can be used with all reagent lots. The exact lot-specific calibrator values are encoded in the barcode as well as printed (or electronically available) on the calibrator barcode sheet. To prepare, carefully dissolve the contents of one bottle by adding exactly 1.0 mL of deionized water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding foam formation. Transfer aliquots of the reconstituted calibrators into empty CalSet vials. Attach the supplied labels to these vials. Roche recommends performing only one calibration procedure per aliquot. The lyophilized calibrators are stable up to the stated expiration date. Aliquots intended for storage should be frozen at -20°C. Reconstituted calibrator is stable for 8 weeks at -20°C (freeze only once). Store calibrators upright in order to prevent the calibrator solution from adhering to the snap-cap.

Traceability: The Elecsys FT3 assay (REF 03051986) has been standardized against the Elecsys FT3 assay (REF 11731386). This in turn was standardized using equilibrium dialysis.

Calibration frequency: Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer).

Renewed calibration is recommended as follows:

•After 1 month (28 days) when using the same reagent lot

•After 7 days (when using the same reagent kit on the analyzer)

•As required: e.g. quality control findings outside the defined limits. Monitor control values to determine stability of the current calibration.

If calibration fails perform the following corrective action steps in sequence:

•Check reagent and calibrator for appropriate lot numbers, expiration dates, preparation, and storage conditions.

•Repeat calibration with new calibrator.

•Repeat calibration with new reagent and new calibrator

•If successful calibration is not achieved, discontinue testing and notify the supervisor.

8. OPERATING PROCEDURE INSTRUCTIONS; CALCULATIONS; INTERPRETATION OF RESULTS

a. **Instrument Operation:** The Roche/Hitachi Cobas 6000 analyzer series is a fully automated, random-access, software controlled system for immunoassay and photometric analyses intended for qualitative and quantitative in vitro determinations using a wide variety of tests. The Cobas 6000 analyzer series is optimized for workloads using a combination of photometric and ion-selective electrode (ISE) determinations (c501 module), and electrochemiluminescence (ECL) signal in the immunoassay analysis module (e601 module). The ISE system is used in the quantitation of sodium, potassium and chloride. The photometric system can measure colorimetric or immunoturbidimetric reactions utilizing end point or kinetic (rate) absorbance measurements. Test ordering end execution on the Cobas 6000 and data entry in the STARLIMS host computer system may be done manually or

these tasks may be executed via a barcode-based bi-directional interface. The Cobas 6000 can utilize both of these two systems simultaneously.

b. **Professional Judgement:** Check results for error flags and take appropriate corrective action. Investigate alert values and delta checks.

c. **Result Entry**

STARLIMS test code: FT3

- Results are reported to one decimal place, as in x.x, in pmol/L.
- Report low results as <0.6 pmol/L.
- Report high results as >50.0 pmol/L.
- Check results for error flags and take appropriate corrective action.
- Investigate alert values and delta checks.

9. REPORTABLE RANGE OF RESULTS

Out of Range results: Certain tests have pre-programmed limits that trigger an automatic re-analysis by the COBAS. These limits may be low-end values or high-end values (but within technical range). If the duplicate value is in agreement with the initial value, then the initial value is reported.

Results are reported to one decimal place, as in x.x, in pmol/L. Report low results as <0.6 pmol/L.

a. Reportable Range of Test Results: Reportable Range 0.6-50 pmol/L

Intra-assay %CV (10 within-day replicates at a concentration of 5.81 pmol/L) 1.7%

Intra-assay %CV (10 within-day replicates at a concentration of 22.41 pmol/L) 1.7%

Inter-assay %CV (49 between day replicates at a concentration of 5.79 pmol/L) 3.0%

Inter-assay %CV (49 between day replicates at a concentration of 22.22 pmol/L) 2.6%

Dilutions: The confirmed analytical measurement range of the assay is 0.6-50 pmol/L.

Samples for FT3 determinations cannot be diluted, as T3 in the blood is present in free and protein-bound forms which are in equilibrium. A change in the concentration of the binding proteins alters this equilibrium.

Reference Ranges:

•Roche Range:

Shared Male/Female: 3.1 – 6.9 pmol/L

•Advanced Research and Diagnostic Laboratory ranges:

Same as Roche range.

Critical Results: None

Analytical Measurement Range: 0.6-50 pmol/L

Reportable Range: 0.6-50 pmol/L

Limit of Detection (standard 1 + 2 SD): 0.6 pmol/L

10. QUALITY CONTROL (QC) PROCEDURE

•Roche PreciControl Universal: Ref. # 11731416 160. 4 x 3.0 mL for each level, PreciU1 and PreciU2. To prepare, carefully dissolve the contents of one bottle by adding exactly 3.0 mL of deionized water and allow to stand closed for 30 minutes to reconstitute. Mix carefully, avoiding foam formation. Transfer aliquots of the freshly reconstituted controls into empty labeled ControlSet Vials. Attach the supplied labels to the additional bottles. Roche recommends performing only one control procedure per aliquot. The lyophilized controls are stable up to the stated expiration date. Aliquots intended for storage should be frozen immediately at -20 °C. Reconstituted control is stable for three months at -20°C (freeze only once) or at 2-8°C for 3 days. Store calibrators upright in order to prevent the calibrator solution from adhering to the snap-cap.

•Both levels of quality control are analyzed at the start of the day and results are verified for acceptability prior to testing specimens. Quality control is also analyzed at the end of the shift, with change in reagent, after major maintenance, or as needed for troubleshooting.

• The analytical measurement range (AMR) must be validated every 6 months or after major maintenance or service procedures. Use Roche FT3 CalCheck (ref#

03554538 190 Roche Diagnostics 9115 Hague Road Indianapolis, IN 46250-0457). Stable until expiration date on package when unopened and stored at 2–8oC. To prepare, reconstitute the contents of each CalCheck vial with exactly 1.0 mL DI water using a volumetric pipet; cap and allow to sit for 15 minutes. Mix by gentle inversion. Reconstituted, the product is stable for 4 hours at 20-25oC. Analyze the samples in triplicate, programming in the same manner as patient samples. Determine the mean value for each level and compare it to the acceptable range listed on the lot-specific value sheet. The recovery values from the instrument should be within the range listed.

•New Lot Verification: Each new reagent lot must be verified for acceptability before being placed into use. Calibration, quality control, and comparison of at least 5 patient samples on the old and new lots must be performed and found to be within acceptable limits before a new lot can be placed into use.

11. REMEDIAL ACTION IF CALIBRATION OR QC SYSTEMS FAIL TO MEET ACCEPTABLE CRITERIA

- If QC values are outside of specified ranges, do the following, in order, until QC is acceptable:

1. Repeat the analysis using fresh QC material.
2. Perform a calibration.
3. Check for system problems.
4. Contact Roche Technical Support for assistance and possible service dispatch. Phone: 1-800-428-2336; account number: 55042919

12. LIMITATIONS OF METHOD; INTERFERING SUBSTANCES AND CONDITIONS

a. Limit of Detection (standard 1 + 2 SD): 0.6 pmol/L

b. Analytical Measurement Range: 0.6-50 pmol/L

c. Interfering Substances and Conditions
•Icteric index < 66: no interference.
•Hemolytic index < 1000: no interference.

•Lipemic index < 2000: no interference.

•Biotin < 70 ng/mL: no interference. In patients receiving therapy with high biotin doses (i.e. > 5 mg/day), no sample should be taken until at least 8 hours after the last biotin administration.

•No interference was observed from rheumatoid factors up to a concentration of 1200 IU/mL.

•Any influence that might affect the binding behavior of the binding proteins can alter the result of the FT3 tests (e.g. drugs, NTIs (Non-Thyroid Illness) or patients suffering from FDH (Familial Dysalbuminemic Hyperthyroxinemia).

•In vitro tests were performed on 17 commonly used pharmaceuticals. No interference with the assay was found.

•In in vitro studies the drugs Furosemide and Levothyroxine caused elevated FT3 findings at the daily therapeutic dosage level.

•In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. These effects are minimized by suitable test design.

13. REFERENCE RANGES (NORMAL VALUES)

•Roche Range:

Shared Male/Female: 3.1 – 6.9 pmol/L

•Advanced Research and Diagnostic Laboratory ranges:

Same as Roche range.

14. CRITICAL CALL RESULTS ("PANIC VALUES")

Not applicable for this procedure.

15. SPECIMEN STORAGE AND HANDLING DURING TESTING

Specimens are frozen at -70°C between sample receipt and analysis on the instrument. Specimens must be at room temperature prior to assay. Specimens are returned to refrigerated or frozen temperature post analysis depending on the study specific requirements.

16. ALTERNATE METHODS FOR PERFORMING TEST OR STORING SPECIMENS IF TEST SYSTEM FAILS

Should the testing system become inoperable, discontinue testing and notify the supervisor. While instrument trouble-shooting or repair occurs; keep specimens at refrigerated or frozen temperature depending on study specific requirements.

17. TEST RESULT REPORTING SYSTEM; PROTOCOL FOR REPORTING CRITICAL CALLS (IF APPLICABLE)

All data is reported electronically via an eFile that is uploaded to the WESTAT secure website within 21 days of receipt of specimens.

18. TRANSFER OR REFERRAL OF SPECIMENS; PROCEDURES FOR SPECIMEN ACCOUNTABILITY AND TRACKING

Specimen Receipt:

Shipments for NHANES generally will arrive on Tuesdays and/or Wednesdays. These shipments are recorded on the Log of Quality Assurance located in a binder labeled NHANES Shipping Log in the receiving area. The specimen barcode numbers in the boxes are checked against the manifests. The receipt date is written on top of the boxes. The frozen samples (vial 118) are placed in the designated -70°C freezer until analysis. The manifests are filed in a binder labeled NHANES Shipping Manifests located in the receiving area. All labels are removed from the shipping box and the provided airbill is attached for return shipment.

Quality Assurance Log:

A Quality Assurance Specimen Receipt and Specimen Return Log is maintained by laboratory staff. The following parameters are tracked: NHANES shipper I.D., NHANES Container I.D., Vial #, Date Received, Specimen Receipt Conditions, Number of Specimens Received, 2.5% QC Repeats, Total Number of Specimens, 21 Day Due Date, Analysis Date, Date Results Sent, Number of Days For Result Return, Thaw Date (if applicable), Return To Freezer Date, 1 Year Discard or Return Date, and NHANES Quarterly Report Date.

QUALITY ASSURANCE SPECIMEN RECEIPT					# received, analyzed		
NHANES	NHANES			receive	and transmitted		
shipper	container		date	spec.		qc rpts	
I.D.	I.D. #	vial #	rec'd	cond.	spec.	COBAS & IMMULITE	total
774903957877	401219	118	4/9/2019	Ok	30	2	32
774965044160	401275	118	4/16/2019	Ok	8	2	10
774965218515	402034	118	4/16/2019	Ok	37	2	39
775015603793	401319	118	4/22/2019	Ok	5	2	7
775021014447	402098	118	4/23/2019	Ok	25	2	27
775078062025	402152	118	4/30/2019	Ok	30	2	32
775078790984	403034	118	4/30/2019	Ok	14	2	16
775135902127	402211	118	5/7/2019	Ok	20	2	22
775137049487	403077	118	5/7/2019	Ok	20	2	22
775195775497	403126	118	5/14/2019	Ok	14	2	16
775196146284	402259	118	5/15/2019	Ok	10	2	12
775255488432	403175	118	5/21/2019	Ok	21	2	23

QUALITY ASSURANCE OF SPECIMEN RETURN							1 year	
	COBAS	IMMULITE (TGN)	date	# days		return to	discard	NHANES
21-day	analyzed	analyzed	result	results	thaw	ARDL freezer	or return	Quarterly
due date	date	date	sent	return	date	date	date	Report
4/30/2019	5/22/2019	5/24/2019	5/28/2019	49	5/22/2019	6/12/2019		
5/7/2019	5/28/2019	5/29/2019	5/31/2019	45	5/28/2019	6/12/2019		
5/7/2019	5/30/2019	6/4/2019	6/11/2019	56	5/30/2019	6/12/2019		
5/13/2019	5/29/2019	5/31/2019	6/5/2019	44	5/29/2019	6/12/2019		
5/14/2019	6/3/2019	6/5/2019	6/11/2019	49	6/3/2019	6/12/2019		
5/21/2019	6/4/2019	6/6/2019	6/11/2019	42	6/4/2019	6/12/2019		
5/21/2019	6/4/2019	6/6/2019	6/11/2019	42	6/4/2019	6/12/2019		
5/28/2019	6/5/2019	6/7/2019	6/13/2019	37	6/5/2019	7/11/2019		
5/28/2019	6/3/2019 & 6/4/2019	43621	6/11/2019	35	6/3/2019	6/12/2019		
6/4/2019	6/5/2019	6/7/2019	6/13/2019	30	6/5/2019	7/11/2019		
6/5/2019	6/10/2019	6/12/2019	6/19/2019	35	6/10/2019	7/11/2019		
6/11/2019	6/11/2019	6/14/2019	6/19/2019	29	6/11/2019	7/11/2019		

Specimen Ordering/Labeling:

Electronic files for all NHANES specimens are sent via email from Westat, Inc to the NHANES contact person shortly before they are to be received. These files include the Sample ID, Analyte Type, Slot No, Sample Collection Date, Sample Comment, Age Grouping, Astro ID, Receipt Date, Analysis Date, Run Number, Tech ID, Analyte Result, Result Comment, Adjusted Result, QC Repeat, LOD, Change Reason, and Change Reason Other. The first seven columns are protected and cannot be altered. The files are saved on the laboratory's common S drive in the NHANES Thyroid folder. After analysis, the contact person returns the completed files via their website to Westat, Inc.

The NHANES spreadsheets are used to set up pending batches for batch accession upload in the Laboratory Information system (STARLIMs). New labels are generated out of the Laboratory Information System (STARLIMs). The new bar-coded labels are

attached to a carrier tube. The Cobas analyzer reads the bar-coded label for the sample ID and test information.

Specimen Storage:

The temperatures for all freezers and refrigerators are monitored 24 hours a day/ 7 days a week. If the temperature for any unit falls outside the allowable range, action is taken to resolve the problem. If the temperature cannot be corrected, the contents are moved to a different unit.

Specimen Handling/Specimen Return:

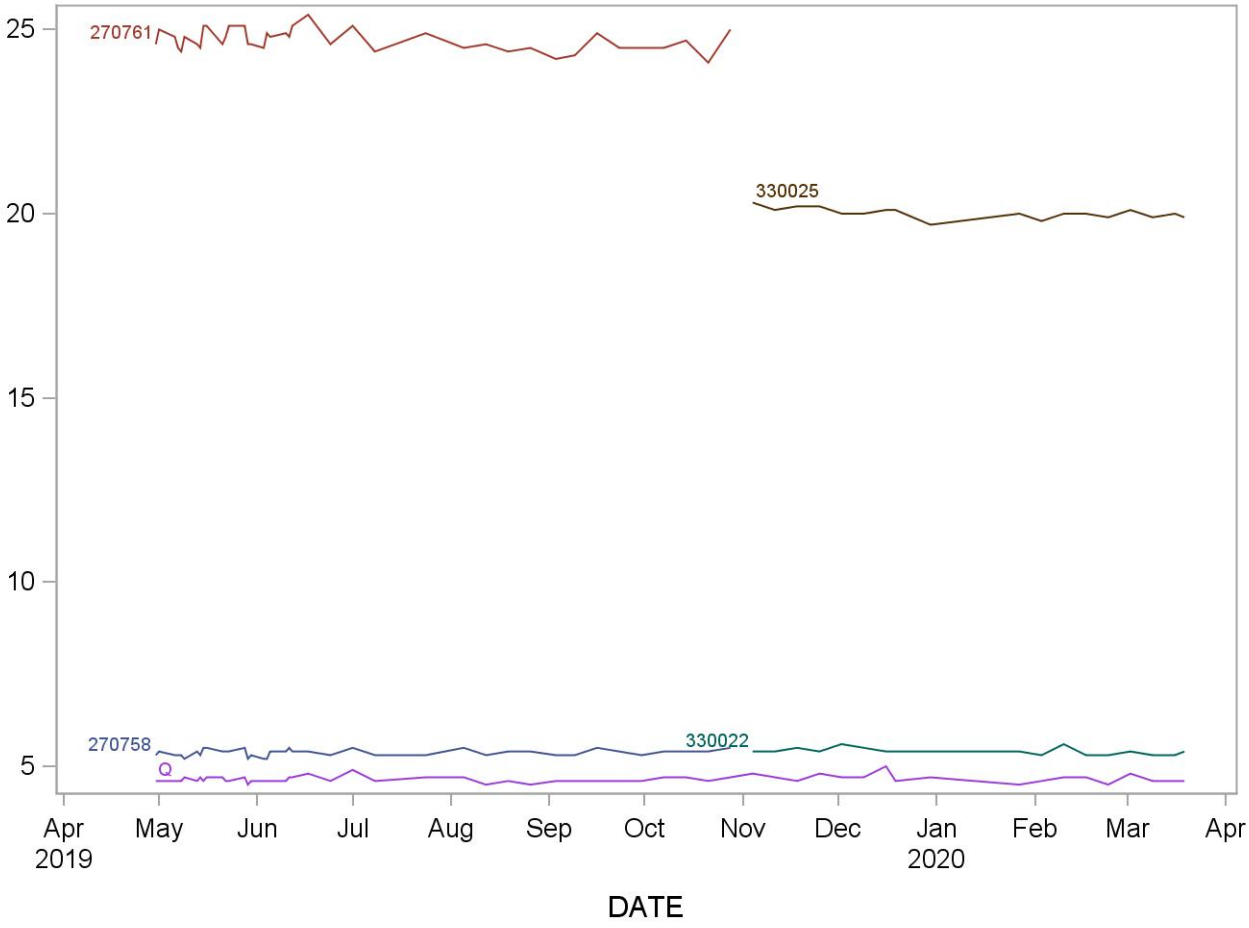
Prior to analysis, the specimens are stored in the designated -70°C freezer. On the day of analysis, the specimens are selected and thawed by the technician operating the COBAS. After analysis and the QC repeats have been run, the specimens are refrozen. After 1 year, the specimen vials that have at least 0.2ml of sample remaining will be shipped to SriSai Biopharmaceuticals in Frederick, MD. These specimens will be shipped on dry ice via Federal Express.

19. SUMMARY STATISTICS AND QC GRAPHS

See following page(s).

2019-2020 Summary Statistics and QC Chart
LBXT3F (Triiodothyronine, free (FT3) (pmol/L))

Lot	N	Start Date	End Date	Mean	Standard Deviation	Coefficient of Variation
270761	40	30APR19	28OCT19	24.71	0.29	1.2
Q	58	30APR19	19MAR20	4.65	0.09	2.0
270758	40	30APR19	28OCT19	5.37	0.09	1.7
330025	18	04NOV19	19MAR20	20.02	0.15	0.7
330022	18	04NOV19	19MAR20	5.41	0.09	1.7



REFERENCES

- Cobas 6000 Analyzer Operator's Manual. Roche Diagnostics Inc., 9115 Hague Road Indianapolis, IN 46250-0457. Version 5.0.
- Roche FT3 reagent package insert. Version 2016-07, V 2.0 English. Roche Diagnostics Inc., 9115 Hague Road Indianapolis, IN 46250-0457.
- Roche FT3 CalSet package insert. Version 2017-02, V 4.0 English. Roche Diagnostics Inc., 9115 Hague Road Indianapolis, IN 46250-0457.
- Roche PreciControl Universal package insert. Version 2015-02, V 9.0. Roche Diagnostics Inc., 9115 Hague Road Indianapolis, IN 46250-0457.
- FT3 Calcheck package insert. Version 2017-09, V 26.0 English. Roche Diagnostics Inc., 9115 Hague Road Indianapolis, IN 46250-0457.