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ACCESS
Immunoassay Systems

Instructions For Use

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Access TSH (3rd IS)
Thyrotropin

REF B63284

FOR PROFESSIONAL USE ONLY

ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

PRINCIPLE

INTENDED USE

The Access TSH (3rd IS) assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of human thyroid-stimulating hormone (thyrotropin, TSH, hTSH) levels in human serum and plasma using the Access Immunoassay Systems. This assay is capable of providing 3rd generation TSH results.

SUMMARY AND EXPLANATION

Human thyroid-stimulating hormone is a glycoprotein hormone consisting of two noncovalently-bound subunits: an α subunit, which is nearly identical to the α subunits of human luteinizing hormone (hLH), human follicle-stimulating hormone (hFSH), and human chorionic gonadotropin (hCG), and a β subunit, which is responsible for immunological and biological specificity.[1]

TSH, released from the anterior pituitary, is the principal regulator of thyroid function, stimulating the synthesis and release of thyroid hormones thyroxine (T4) and triiodothyronine (T3). T3 and T4 regulate biochemical processes that are essential for normal metabolism. The synthesis and secretion of TSH is stimulated by thyrotropin-releasing hormone (TRH), which is produced by the hypothalamus in response to low levels of circulating T3 and T4. In contrast, elevated levels of T3 and T4 suppress the production of TSH. Collectively, this negative feedback system is referred to as the hypothalamic-pituitary-thyroid axis. Any alteration in the function of this axis can influence the levels of TSH, T4, and T3 in circulation.[1]

The principal clinical use for TSH measurement is for the assessment of thyroid status. TSH is measured in conjunction with thyroid hormones or antibodies to: 1) detect or exclude hypothyroidism or hyperthyroidism; 2) monitor T4 replacement treatment in hypothyroidism or antithyroid treatment in hyperthyroidism; 3) monitor TSH suppression in thyroid cancer patients on thyroxine therapy; and 4) assess the response to TRH stimulation testing.[2,3]

Reference ranges for TSH may vary, depending on the method of analysis, and do not necessarily equate to cut-offs for diagnosing thyroid dysfunction.

As methods achieving third-generation sensitivity have become available, TSH measurements are also used to identify subclinical or latent hypothyroidism or hyperthyroidism. Third generation methods for TSH measurement are defined

as achieving a functional sensitivity of 0.01-0.02 µIU/mL (mIU/L) with an interassay %CV ≤ 20%.[4,5] Clinical laboratories may use these more sensitive and precise methods to distinguish different levels of TSH suppression associated with Graves' disease and subclinical hyperthyroidism and to assist in the diagnosis of gestational and postpartum thyroid diseases.[3,6,7]

METHODOLOGY

The Access TSH (3rd IS) assay is a two-site immunoenzymatic ("sandwich") assay. A sample is added to a reaction vessel with mouse anti-hTSH-alkaline phosphatase conjugate, buffered protein solution and paramagnetic particles coated with immobilized mouse monoclonal anti-hTSH antibody. The hTSH binds to the immobilized monoclonal anti-hTSH antibody on the solid phase while the mouse anti-hTSH-alkaline phosphatase conjugate reacts with a different antigenic site on the hTSH. After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Then, the chemiluminescent substrate Lumi-Phos* 530 is added to the vessel and light generated by the reaction is measured with a luminometer. The light production is directly proportional to the concentration of TSH in the sample. The amount of analyte in the sample is determined from a stored, multi-point calibration curve.

SPECIMEN

SPECIMEN COLLECTION AND PREPARATION

1. Serum (gel and no gel) and plasma (lithium heparin) are the recommended samples.
2. The role of preanalytical factors in laboratory testing has been described in a variety of published literature.[8,9] To minimize the effect of preanalytical factors observe the following recommendations for handling, processing, and storing blood samples:[8]
   - Collect all blood samples observing routine precautions for venipuncture.
   - Allow serum samples to clot completely before centrifugation in a vertical, closure-up position.
     - Nonanticoagulated tubes containing gel separator should be stored in an upright position as soon as the mixing is complete.
     - Precentrifugation serum/cells contact time is according to tube manufacturer's recommendations. Clotting may be slowed at cooler temperatures or if patient is on anticoagulant therapy.
   - Keep tubes stoppered at all times.
   - Physically separate serum or plasma from contact with cells as soon as possible. Tightly stopper the tube immediately.
   - Store samples tightly stoppered at room temperature (15 to 30°C) for up to 18 hours.
   - If the assay will not be completed within 18 hours, refrigerate the samples at 2 to 8°C.
   - If the assay will not be completed within seven days, freeze at -20°C or colder.
   - Frozen specimens can be stored up to 90 days before testing.
   - Do not thaw samples more than two times.
3. Use the following guidelines when preparing specimens:
   - Ensure residual fibrin and cellular matter have been removed prior to analysis.
   - Follow blood collection tube manufacturer's recommendations for centrifugation.
4. Each laboratory should determine the acceptability of its own blood collection tubes and serum separation products. Variations in these products may exist between manufacturers and, at times, from lot-to-lot.
5. Avoid assaying lipemic or hemolyzed samples.

REAGENTS

PRODUCT INFORMATION

Access TSH (3rd IS) Reagent Pack

Cat. No. B63284: 200 determinations, 2 packs, 100 tests/pack

- Provided ready to use.
- Store upright and refrigerate at 2 to 10°C.
- Refrigerate at 2 to 10°C for a minimum of two hours before use on the instrument.
- Stable until the expiration date stated on the label when stored at 2 to 10°C.
- Stable at 2 to 10°C for 28 days after initial use.
- Signs of possible deterioration are a broken elastomeric layer on the pack or quality control values out of range.
- If the reagent pack is damaged (e.g., broken elastomer), discard the pack.

R1a:	Paramagnetic particles coated with mouse monoclonal anti-human TSH antibody suspended in TRIS buffered saline, with surfactant, bovine serum albumin (BSA), < 0.1% sodium azide, and 0.1% ProClin** 300.
R1b:	TRIS buffered saline with surfactant, BSA, protein (murine), < 0.1% sodium azide, and 0.1% ProClin 300.
R1c:	Mouse monoclonal anti-human TSH alkaline phosphatase conjugate in ACES buffered saline, with surfactant, BSA matrix, protein (murine), < 0.1% sodium azide, and 0.25% ProClin 300.
R1d:	Mouse monoclonal anti-human TSH alkaline phosphatase conjugate in ACES buffered saline, with surfactant, BSA matrix, protein (murine), < 0.1% sodium azide, and 0.25% ProClin 300.

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WARNING AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Patient samples and blood-derived products may be routinely processed with minimum risk using the procedure described. However, handle these products as potentially infectious according to universal precautions and good clinical laboratory practices, regardless of their origin, treatment, or prior certification. Use an appropriate disinfectant for decontamination. Store and dispose of these materials and their containers in accordance with local regulations and guidelines.
- For hazards presented by the product refer to the following sections: REACTIVE INGREDIENTS and GHS HAZARD CLASSIFICATION.

REACTIVE INGREDIENTS

⚠ CAUTION

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

GHS HAZARD CLASSIFICATION

TSH Particles (Compartment R1a)	WARNING	
		
	H316	Causes mild skin irritation.
	H317	May cause an allergic skin reaction.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P332+P313	If skin irritation occurs: Get medical advice/attention.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		Tris(hydroxymethyl)– aminomethane 1 - 5%
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%
TSH Ancillary (Compartment R1b)	WARNING	
		
	H316	Causes mild skin irritation.
	H317	May cause an allergic skin reaction.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P332+P313	If skin irritation occurs: Get medical advice/attention.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		Tris(hydroxymethyl)– aminomethane 1 - 5%
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%
TSH Conjugate (Compartment R1c)	WARNING	
		
	H317	May cause an allergic skin reaction.

	P280	Wear protective gloves, protective clothing and eye/face protection.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%
TSH Conjugate (Compartment R1d)	WARNING	
		
	H317	May cause an allergic skin reaction.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

SDS	Safety Data Sheet is available at techdocs.beckmancoulter.com

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

1. Access TSH (3rd IS) Calibrators
   Provided at zero and approximately 0.050, 0.30, 3.0, 15.0 and 50.0 µIU/mL (mIU/L).
   Cat. No. B63285
2. Quality Control (QC) materials: commercial control material.
3. Access Substrate
   Cat. No. 81906
4. **Access 2 Immunoassay Systems:**
   Access Wash Buffer II, Cat. No. A16792
   UniCel DxI Immunoassay Systems:
   UniCel DxI Wash Buffer II, Cat. No. A16793

EQUIPMENT AND MATERIALS

R1	Access TSH (3rd IS) Reagent Packs

CALIBRATION

CALIBRATION INFORMATION

An active calibration curve is required for all tests. For the Access TSH (3rd IS) assay, calibration is required every 28 days. Refer to the appropriate system manuals and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.

QUALITY CONTROL

Quality control materials simulate the characteristics of patient samples and are essential for monitoring the system performance of immunochemical assays. Because samples can be processed at any time in a "random access" format rather than a "batch" format, quality control materials should be included in each 24-hour time period.[10] Include commercially available quality control materials that cover at least two levels of analyte. More frequent use of controls or the use of additional controls is left to the discretion of the user based on good laboratory practices or laboratory accreditation requirements and applicable laws. Follow manufacturer's instructions for reconstitution and storage. Each laboratory should establish mean values and acceptable ranges to assure proper performance. Quality control results that do not fall within acceptable ranges may indicate invalid test results. Examine all test results generated since obtaining the last acceptable quality control test point for this analyte. Refer to the appropriate system manuals and/or Help system for information about reviewing quality control results.

TESTING PROCEDURE(S)

PROCEDURAL COMMENTS

1. Refer to the appropriate system manuals and/or Help system for a specific description of installation, start-up, principles of operation, system performance characteristics, operating instructions, calibration procedures, operational limitations and precautions, hazards, maintenance, and troubleshooting.
2. Mix contents of new (unpunctured) reagent packs by gently inverting pack several times before loading on the instrument. Do not invert open (punctured) packs.
3. Use fifty-five (55) µL of sample for each determination in addition to the sample container and system dead volumes when requesting the assay (test name: TSH3). Use fifty (50) µL of sample in addition to the sample container and system dead volumes for each determination run with the special dilution feature (test name: TSH3d). Refer to the appropriate system manuals and/or Help system for the minimum sample volume required.
4. The system default unit of measure for sample results is µIU/mL. To change sample reporting units to the International System of Units (SI units), mIU/L, refer to the appropriate system manuals and/or Help system. To manually convert concentrations to the International System, multiply µIU/mL by multiplication factor 1.

PROCEDURE

Refer to the appropriate system manuals and/or Help system for information on managing samples, configuring tests, requesting tests, and reviewing test results.

- Select TSH3 as the test name for assaying samples containing hTSH concentrations up to the concentration of the Access TSH (3rd IS) S5 calibrator.
- Use the special dilution feature (test name: TSH3d) for assaying samples containing hTSH concentrations greater than the Access TSH (3rd IS) S5 calibrator.

RESULTS INTERPRETATION

Test results are determined automatically by the system software. The amount of analyte in the sample is determined from the measured light production by means of the stored calibration data. Test results can be reviewed using the

appropriate screen. Refer to the appropriate system manuals and/or Help system for complete instructions on reviewing sample results.

REPORTING RESULTS

EXPECTED RESULTS

1. Each laboratory should establish its own reference intervals to assure proper representation of specific populations.
2. Beckman Coulter conducted a multicenter prospective study across geographically diverse locations to establish the central 97.5% reference interval in apparently healthy, euthyroid adults. Subjects with no known personal or family thyroid disease, goiter, chronic disease (including cancer, diabetes, autoimmune disease, or cardiovascular disease), acute bacterial or viral infection, or current use of prescription medication (excluding prenatal vitamins) or aspirin were enrolled in the study, following the guidance of both the National Academy of Clinical Biochemistry's (NACB) Laboratory Medicine Practice Guideline, Laboratory Support for the Diagnosis and Monitoring of Thyroid Disease, and the Third National Health and Nutrition Examination Survey (NHANES III). [3,11]

   The study included four populations: a general population of approximately equal numbers of males and non-pregnant females between the ages of 18-88; and pregnant females with approximately equal distribution across all three trimesters. Trimesters were defined according to American Congress of Obstetricians and Gynecologists guidelines.[12] Approximately four hundred (400) subjects were enrolled in each population.

   After enrollment, subjects' samples were screened for positive thyroid peroxidase antibody (TPOAb) and thyroglobulin antibody (TgAb) using the Beckman Coulter Access TPO Antibody and Access Thyroglobulin Antibody II assays prior to analyses. Samples with positive TPOAb or TgAb results (approximately 10%) were excluded from analysis of the TSH reference intervals.

   Serum samples were analyzed using multiple UniCel DxI 800 Access Immunoassay Systems with the Access TSH (3rd IS) assay, following the CLSI EP28-A3c guideline.[13] The observed non-parametric ranges of TSH concentrations are shown below for each population tested.

Population	Sample Size	Median (µIU/mL)	97.5% Reference Interval (µIU/mL)
General Population (males and non-pregnant females, aged 18-88)	393	1.45	0.38 - 5.33
Pregnant Females, 1st Trimester	318	1.13	0.05 - 3.70
Pregnant Females, 2nd Trimester	362	1.47	0.31 - 4.35
Pregnant Females, 3rd Trimester	335	1.61	0.41 - 5.18

3. For additional reference interval guidance, refer to the National Academy of Clinical Biochemistry (NACB) publication, Laboratory Support for the Diagnosis and Monitoring of Thyroid Disease, and the Third National Health and Nutrition Examination Survey (NHANES III).[3,11]
4. The evaluation of thyroid status should not depend on results from a single test. Complete thyroid status evaluation should include other thyroid function tests, including evaluation of thyroid autoantibodies (useful in the diagnosis of autoimmune thyroiditis), and the physician's clinical evaluation.

PROCEDURAL NOTES

LIMITATIONS

1. Samples can be accurately measured within the analytical range of the Limit of Detection (LoD) and the highest calibrator value (approximately 0.005 - 50.0 µIU/mL [mIU/L]).

   - If a sample contains less than the lower Limit of Detection (LoD) for the assay, report the result as less than that value (i.e., < 0.005 µIU/mL [mIU/L]).
   - If a sample contains more than the stated value of the highest Access TSH (3rd IS) Calibrator (S5), report the result as greater than that value (i.e., > 50.0 µIU/mL [mIU/L]). Alternatively, dilute one volume of sample with 9 volumes of Access Wash Buffer II or UniCel DxI Wash Buffer II.

     Refer to the appropriate system manuals and/or Help system for instructions on entering a sample dilution in a test request. The system reports the results adjusted for the dilution.

     Dil-TSH (3rd IS) Special Dilution Feature for use on Access 2 and UniCel DxI systems:

     Samples containing hTSH concentrations greater than the concentration of the Access TSH (3rd IS) S5 calibrator can be processed using the Special Dilution Feature. When TSH3d is requested, the system automatically dilutes the sample using Wash Buffer II and reads the resulting dose off the TSH3 calibration curve.

Test Name	Reportable Range (µIU/mL)	Sample Volume Required
TSH3d	37.5 - 500	50 µL

2. For assays employing antibodies, the possibility exists for interference by heterophile antibodies in the patient sample. Patients who have been regularly exposed to animals or have received immunotherapy or diagnostic procedures utilizing immunoglobulins or immunoglobulin fragments may produce human anti-animal antibodies, e.g. HAMA, that interfere with immunoassays.[14,15] Such interfering antibodies may cause erroneous results. Carefully evaluate the results of patients suspected of having these antibodies.
3. Other potential interferences in the patient sample could be present and may cause erroneous results in immunoassays. Some examples that have been documented in literature include rheumatoid factor, endogenous alkaline phosphatase, fibrin, and proteins capable of binding to alkaline phosphatase.[16] Carefully evaluate results if the sample is suspected of having these types of interferences.
4. The Access TSH (3rd IS) results should be interpreted in light of the total clinical presentation of the patient, including: symptoms, clinical history, data from additional tests, and other appropriate information.
5. The Access TSH (3rd IS) assay does not demonstrate any “hook” effect up to 1,000 µIU/mL (mIU/L).
6. This assay is not validated for testing neonatal serum hTSH levels.

PERFORMANCE CHARACTERISTICS

PERFORMANCE CHARACTERISTICS

METHODS COMPARISON

Representative data for methods comparison are provided for illustration only. Performance obtained in individual laboratories may vary.

A comparison of 207 samples using the Access TSH (3rd IS) assay on the UniCel DxI 800 Immunoassay System and a commercially available immunoassay kit gave the following statistical data using Passing-Bablok regression and Pearson’s correlation, following the CLSI EP9-A3 guideline:[17]

n	Range of Observations† (µIU/mL)	Intercept (µIU/mL) [95% CI]	Slope (95% CI)	Correlation Coefficient (r)
207	0.010 - 44.90	-0.04 [-0.05 - (-0.02)]	0.91 (0.88 - 0.92)	0.99

†Observed concentration range of the Access TSH (3rd IS) assay.

LINEARITY

Representative data for linearity are provided for illustration only. Performance obtained in individual laboratories may vary.

Based on CLSI EP6-A[18], one high sample [approximately 50.0 µIU/mL (mIU/L)] and one low sample [< 0.005 µIU/mL (mIU/L)] were mixed to make nine sample concentrations evenly distributed across the analytical measuring range. Four replicates of the seven mixed samples, eight replicates of the low sample, and four replicates of the high sample were tested on one UniCel DxI 800 Immunoassay System. The Access TSH (3rd IS) assay demonstrated acceptable linearity throughout the analytical measuring range of 0.005 to approximately 50.0 µIU/mL (mIU/L).

DILUTION RECOVERY

Representative data for dilution recovery are provided for illustration only. Performance obtained in individual laboratories may vary.

Four serum samples at concentrations above the Access TSH (3rd IS) S5 calibrator [approximately 50.0 µIU/mL (mIU/L)] were diluted 1/10 with Wash Buffer II. Twenty-four replicates for each sample were measured on one UniCel DxI 800 Immunoassay System, providing the following data:

Sample	Target Concentration (µIU/mL)	Dil-TSH (3rd IS) Sample Mean Recovery (%)	Manual Dilution Sample Mean Recovery (%)
Sample 1	100	97	96
Sample 2	200	98	95
Sample 3	300	93	95
Sample 4	400	93	93

IMPRECISION

Representative data for imprecision are provided for illustration only. Performance obtained in individual laboratories may vary.

The Access TSH (3rd IS) assay exhibits total imprecision ≤ 10% CV at concentrations > 0.02 µIU/mL (mIU/L) and total standard deviation (SD) ≤ 0.0029 µIU/mL (mIU/L) at concentrations ≤ 0.02 µIU/mL (mIU/L).

One study, using four serum-based samples on one UniCel DxI 800 Immunoassay System, generating a total of 40 assays, two replicates per assay, over 20 days with two runs per day, provided the following data, calculated based on the CLSI EP5-A3[19] guideline.

		Within-Run (Repeatability)		Between-Day		Between-Run		Total Imprecision (Within-Laboratory Precision)	
Sample	Grand Mean (µIU/mL) (n=80)	SD (µIU/mL)	(%CV)	SD (µIU/mL)	(%CV)	SD (µIU/mL)	(%CV)	SD (µIU/mL)	(%CV)
Sample 1	0.02	0.0004	N/A	0.0008	N/A	0.0004	N/A	0.0010	N/A
Sample 2	0.37	0.006	2	0.010	3	0.006	2	0.013	3
Sample 3	4.71	0.13	3	0.11	2	0.008	0.2	0.17	4
Sample 4	38.76	1.36	4	1.80	5	0.49	1	2.31	6

ANALYTICAL SPECIFICITY / INTERFERENCES

Representative data for analytical specificity/interferences are provided for illustration only. Performance obtained in individual laboratories may vary.

Serum samples containing hTSH concentrations of approximately 0.30 µIU/mL and 5.0 µIU/mL were spiked with multiple concentrations of the substances below and run on one UniCel DxI 800 Immunoassay System. Values were calculated as described in CLSI EP7-A2.[20] Interference was determined by testing controls (no interfering substance added) and matched test samples (with interfering substance added). Of the compounds tested, none were found to cause significant interference (as defined by a shift in dose greater than 10%) using the highest test concentrations indicated in the table below.

Substance	Highest Concentration Added
Acetaminophen	200 µg/mL
Acetylsalicylic acid	650 µg/mL
Bilirubin (conjugated)	450 µg/mL
Bilirubin (unconjugated)	400 µg/mL
Hemoglobin	10 mg/mL
Heparin (Sodium)	3 U/mL
hGH (Human Growth Hormone)	134 ng/mL
Human Serum Albumin (HSA)	60 mg/mL
Ibuprofen	500 µg/mL
Multivitamin	0.9% (v/v)
Triglycerides (Intra Lipid)	33 mg/mL

A study was performed to evaluate the potential cross-reactivity of the assay with other substances that are similar in structure to hTSH. Serum samples containing hTSH concentrations of approximately 0.30 µIU/mL and 5.0 µIU/mL were spiked with multiple concentrations of the substances below and run on one UniCel DxI 800 Immunoassay System. Values were calculated as described in CLSI EP7-A2.[20]

Samples containing substances at the concentrations listed below do not affect the concentration of hTSH reported.

Substance	Highest Concentration Added (mIU/mL)	Cross-reactivity (%)
hCG	1,000,000	< 0.010%
hFSH	1,000	< 0.10%
hLH	3,000	< 0.10%

Representative data for Limit of Blank, Limit of Detection and Limit of Quantitation are provided for illustration only. Performance obtained in individual laboratories may vary.

LIMIT OF BLANK

The Access TSH (3rd IS) assay is designed to have a Limit of Blank (LoB) of < 0.005 µIU/mL (mIU/L). In one study, LoB was tested using a protocol based on CLSI EP17-A2.[21] A total of 360 replicates of four zero analyte samples were measured in three runs using multiple reagent pack lots and one calibrator lot on multiple UniCel DxI 800 Immunoassay Systems. This study determined the LoB for the Access TSH (3rd IS) assay to be 0.001 µIU/mL (mIU/L), which supports the claim of < 0.005 µIU/mL (mIU/L).

LIMIT OF DETECTION

The Access TSH (3rd IS) assay is designed to have a Limit of Detection (LoD) of ≤ 0.005 µIU/mL (mIU/L). In one study, LoD was tested using a protocol based on CLSI EP17-A2.[21] A total of 675 replicates from five low-level samples were measured using multiple reagent pack lots and one calibrator lot in five runs on multiple UniCel DxI 800 Immunoassay Systems. This study determined the LoD for the Access TSH (3rd IS) assay to be 0.001 µIU/mL (mIU/L), which supports the claim of ≤ 0.005 µIU/mL (mIU/L).

LIMIT OF QUANTITATION

The Access TSH (3rd IS) assay is designed to have a Limit of Quantitation (LoQ) of ≤ 0.01 µIU/mL (mIU/L) at ≤ 10% between-run CV. In one study, LoQ was tested using a protocol based on CLSI EP17-A2.[21] A total of 945 replicates of seven samples were measured using multiple reagent pack lots and one calibrator lot in five runs on one UniCel DxI 800 Immunoassay System. LoQ was determined as the lowest concentration with a between-run imprecision of 10% CV. This study determined the LoQ for the Access TSH (3rd IS) assay to be 0.001 µIU/mL (mIU/L), which supports the claim of ≤ 0.01 µIU/mL (mIU/L) at ≤ 10% between-run CV.

ADDITIONAL INFORMATION

Beckman Coulter, the stylized logo, and the Beckman Coulter product and service marks mentioned herein are trademarks or registered trademarks of Beckman Coulter, Inc. in the United States and other countries.

* Lumi-Phos is a trademark of Lumigen, Inc., a subsidiary of Beckman Coulter, Inc.

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