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# Thyroid Stimulating Hormone 3-Ultra (TSH3-UL)

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| **Current Revision and Date**[a] | Rev. 04, 2021-03 | |
| **Product Name** | Atellica IM Thyroid Stimulating Hormone 3-Ultra (TSH3-UL) | REF 10995703 (110 tests)<br>REF 10995704 (550 tests) |
| **Abbreviated Product Name** | Atellica IM TSH3-UL | |
| **Test Name/ID** | TSH3UL | |
| **Systems** | Atellica IM Analyzer | |
| **Optional Materials** | Atellica IM TSH3-UL MCM | REF 10995705 |
| **Specimen Types** | Serum, EDTA plasma, lithium heparin plasma | |
| **Sample Volume** | 75 µL | |
| **Measuring Interval** | 0.008–150.000 µIU/mL (mIU/L) | |

[a] A vertical bar in the page margin indicates technical content that differs from the previous version.

## Intended Use

The Atellica® IM Thyroid Stimulating Hormone 3-Ultra (TSH3-UL) assay is for *in vitro* diagnostic use in the quantitative determination of thyroid-stimulating hormone (TSH, thyrotropin) in human serum and plasma (EDTA and lithium heparin) using the Atellica® IM Analyzer. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.

## Summary and Explanation

Thyroid-stimulating hormone is a glycoprotein with 2 non-covalently bound subunits. The alpha subunit is similar to those of follicle-stimulating hormone (FSH), human chorionic gonadotropin (hCG), and luteinizing hormone (LH).[1-4]

The beta subunit of TSH is unique, which results in the specific biochemical and immunological properties of this hormone.

TSH is synthesized and secreted by the anterior pituitary in response to a negative feedback mechanism involving concentrations of $FT_3$ (free $T_3$) and $FT_4$ (free $T_4$). Additionally, the hypothalamic tripeptide, thyrotropin-releasing hormone (TRH), directly stimulates TSH production.

TSH interacts with specific cell receptors on the thyroid cell surface and exerts 2 main actions. The first action is to stimulate cell reproduction and hypertrophy. Secondly, TSH stimulates the thyroid gland to synthesize and secrete $T_3$ and $T_4$.

The ability to quantitate circulating levels of TSH is important in evaluating thyroid function. It is especially useful in the differential diagnosis of primary (thyroid) from secondary (pituitary) and tertiary (hypothalamus) hypothyroidism. In primary hypothyroidism, TSH levels are significantly elevated, while in secondary and tertiary hypothyroidism, TSH levels are low.

TRH stimulation differentiates secondary and tertiary hypothyroidism by observing the change in patient TSH levels. Typically, the TSH response to TRH stimulation is absent in cases of secondary hypothyroidism, and normal to exaggerated in tertiary hypothyroidism.

Historically, TRH stimulation has been used to confirm primary hyperthyroidism, indicated by elevated $T_3$ and $T_4$ levels and low or undetectable TSH levels. TSH assays with increased sensitivity and specificity provide a primary diagnostic tool to differentiate hyperthyroid from euthyroid patients.

## Principles of the Procedure

The Atellica IM TSH3-UL assay is a third-generation assay that employs anti-FITC monoclonal antibody covalently bound to paramagnetic particles, an FITC-labeled anti-TSH capture mouse monoclonal antibody, and a tracer consisting of a proprietary acridinium ester and an anti-TSH mouse monoclonal antibody conjugated to bovine serum albumin (BSA) for chemiluminescent detection.

A direct relationship exists between the amount of TSH present in the patient sample and the amount of relative light units (RLUs) detected by the system.

## Reagents

| Material Description | Storage | Stability[a] |
|---|---|---|
| **Atellica IM TSH3-UL ReadyPack® primary reagent pack**<br>**Lite Reagent**<br>4.2 mL/reagent pack<br>Bovine serum albumin (BSA) conjugated to mouse monoclonal anti-TSH (~0.3 µg/mL) labeled with acridinium ester in HEPES buffered saline; mouse IgG; BSA; goat serum; surfactant; preservatives<br>**Solid Phase**<br>16.5 mL/reagent pack<br>Mouse monoclonal anti-fluorescein antibody covalently linked to paramagnetic particles (~85 µg/mL) in buffer; stabilizers; surfactant; preservatives<br>**Ancillary Well Reagent**<br>4.2 mL/reagent pack<br>FITC conjugated to mouse monoclonal anti-TSH (~3 µg/mL) in buffer; stabilizers; surfactant; preservatives | Unopened at 2–8°C<br><br>Onboard | Until expiration date on product<br><br>63 days |
| **Atellica IM TSH3-UL CAL**<br>2.0 mL/vial; lyophilized<br>After reconstitution, low and high levels of thyroid-stimulating hormone (TSH); buffer; equine serum; sodium azide (< 0.1%); preservatives | Lyophilized at 2–8°C<br><br>Reconstituted at 2–8°C<br><br>Reconstituted at room temperature<br><br>Atellica® Sample Handler[b] | Until expiration date on product<br><br>28 days<br><br>4 hours |

[a] Refer to *Storage and Stability*.

[b] Refer to the supplementary document "Atellica Sample Handler Calibrator and QC Storage and Stability" for information about storage and stability of materials in the Cal-QC tube storage area.

## Warnings and Precautions

For *in vitro* diagnostic use.

For Professional Use.

**CAUTION**

Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional.

Safety data sheets (SDS) available on siemens.com/healthineers.

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| **H412** | Harmful to aquatic life with long lasting effects. |
| **P273, P501** | Avoid release to the environment. Dispose of contents and container in accordance with all local, regional, and national regulations.<br>**Contains:** sodium azide (in Atellica IM TSH3-UL CAL) |

**CAUTION**

This device contains material of animal origin and should be handled as a potential carrier and transmitter of disease.

Contains sodium azide as a preservative. Sodium azide can react with copper or lead plumbing to form explosive metal azides. On disposal, flush reagents with a large volume of water to prevent buildup of azides. Disposal into drain systems must be in compliance with prevailing regulatory requirements.

Dispose of hazardous or biologically contaminated materials according to the practices of your institution. Discard all materials in a safe and acceptable manner and in compliance with prevailing regulatory requirements.

**Note** For information about reagent preparation, refer to *Preparing the Reagents* in the *Procedure* section.

**Note** For information about calibrator preparation, refer to *Preparing the Calibrators*.

## Storage and Stability

Store reagents in an upright position. Protect the product from heat and light sources. Unopened reagents are stable until the expiration date on the product when stored at 2–8°C.

Store calibrators in an upright position. Lyophilized calibrators are stable until the expiration date on the product when stored at 2–8°C. Reconstituted calibrators are stable for 28 days at 2–8°C or for 4 hours at room temperature.

Refer to the supplementary document "Atellica Sample Handler Calibrator and QC Storage and Stability" for information about storage and stability of materials in the Cal-QC tube storage area.

Do not use products beyond the expiration date printed on the product labeling.

## Onboard Stability

Reagents are stable onboard the system for 63 days. Discard reagents at the end of the onboard stability interval.

Do not use products beyond the expiration date printed on the product labeling.

# Specimen Collection and Handling

Serum and plasma (EDTA, lithium heparin) are the recommended sample types for this assay.

## Collecting the Specimen

- Observe universal precautions when collecting specimens. Handle all specimens as if they are capable of transmitting disease.[5]
- Follow recommended procedures for collection of diagnostic blood specimens by venipuncture.[6]
- Follow the instructions provided with your specimen collection device for use and processing.[7]
- Allow blood specimens to clot completely before centrifugation.[8]
- Keep tubes capped at all times.[8]
- Complete clot formation should take place before centrifugation. Serum should be physically separated from cells as soon as possible with a maximum limit of 2 hours from the time of collection.[8]
- Do not use samples that have been stored at room temperature for longer than 24 hours.

## Storing the Specimen

- Separated specimens are stable for 24 hours at room temperature or 2 days at 2–8°C. For longer storage, serum and EDTA plasma samples may be frozen for up to 30 days at ≤ -20°C. Lithium heparin samples can be stored at ≤ -20°C for up to 14 days.
- Freeze samples only 1 time and mix thoroughly after thawing. Thawed specimens that are turbid must be clarified by centrifugation prior to testing.

The handling and storage information provided here is based on data or references maintained by the manufacturer. It is the responsibility of the individual laboratory to use all available references and/or its own studies when establishing alternate stability criteria to meet specific needs.

## Transporting the Specimen

Package and label specimens for shipment in compliance with applicable federal and international regulations covering the transport of clinical specimens and etiological agents.

## Preparing the Samples

This assay requires 75 µL of sample for a single determination. This volume does not include the unusable volume in the sample container or the additional volume required when performing duplicates or other tests on the same sample. For information about determining the minimum required volume, refer to the online help.

**Note** Do not use specimens with apparent contamination.

Before placing samples on the system, ensure that samples are free of:

- Bubbles or foam.
- Fibrin or other particulate matter.

**Note** Remove particulates by centrifugation according to CLSI guidance and the collection device manufacturer's recommendations.[8]

**Note** For a complete list of appropriate sample containers, refer to the online help.

# Procedure

## Materials Provided

The following materials are provided:

| REF | Contents | Number of Tests |
|---|---|---|
| 10995703 | 1 ReadyPack primary reagent pack containing Atellica IM TSH3-UL Lite Reagent, Solid Phase, and Ancillary Well Reagent<br>Atellica IM TSH3-UL master curve and test definition MC TDEF<br>1 vial Atellica IM TSH3-UL CAL low calibrator CAL L<br>1 vial Atellica IM TSH3-UL CAL high calibrator CAL H<br>Atellica IM TSH3-UL CAL calibrator lot-specific value sheet CAL LOT VAL | 110 |
| 10995704 | 5 ReadyPack primary reagent packs containing Atellica IM TSH3-UL Lite Reagent, Solid Phase, and Ancillary Well Reagent<br>Atellica IM TSH3-UL master curve and test definition MC TDEF<br>2 vials Atellica IM TSH3-UL CAL low calibrator CAL L<br>2 vials Atellica IM TSH3-UL CAL high calibrator CAL H<br>Atellica IM TSH3-UL CAL calibrator lot-specific value sheet CAL LOT VAL | 550 |

## Materials Required but Not Provided

The following materials are required to perform this assay, but are not provided:

| REF | Description |
|---|---|
| | Atellica IM Analyzer[a] |

[a] Additional system fluids are required to operate the system: Atellica IM Wash, Atellica IM Acid, Atellica IM Base, and Atellica IM Cleaner. For system fluid instructions for use, refer to the Document Library.

## Optional Materials

The following materials may be used to perform this assay, but are not provided:

| REF | Description | |
|---|---|---|
| 10995705 | Atellica IM TSH3-UL MCM (master curve material) | 10 x 2.0 mL levels of master curve material MCM |

## Assay Procedure

The system automatically performs the following steps:

1. Dispenses 75 µL of sample into a cuvette.
2. Dispenses 38 µL of Ancillary Well Reagent and 38 µL of Lite Reagent, then incubates for 5 minutes at 37°C.
3. Dispenses 150 µL of Solid Phase, then incubates for 7 minutes at 37°C.
4. Separates, aspirates, then washes the cuvette with Atellica IM Wash.
5. Dispenses 300 µL each of Atellica IM Acid and Atellica IM Base to initiate the chemiluminescent reaction.
6. Reports results.

## Preparing the Reagents

All reagents are liquid and ready to use. Before loading primary reagent packs onto the system, mix them by hand and visually inspect the bottom of the reagent pack to ensure that all particles are resuspended. For information about preparing the reagents for use, refer to the online help.

## Preparing the System

Ensure that the system has sufficient reagent packs loaded in the reagent compartment. The system automatically mixes reagent packs to maintain homogeneous suspension of the reagents. For information about loading reagent packs, refer to the online help.

### Master Curve Definition

Before initiating calibration on each new lot of reagent, load the assay master curve and test definition values by scanning the MC TDEF 2D barcodes. For loading instructions, refer to the online help.

## Performing Calibration

For calibration of the Atellica IM TSH3-UL assay, use the calibrators provided with each kit.

Do not pour the calibrators back into the vials after calibration because evaporation could occur, which may affect performance.

Do not refill calibrator sample cups when the contents are depleted. If required, dispense fresh calibrators.

### Calibration Frequency

Perform a calibration if one or more of the following conditions exist:

- When changing lot numbers of primary reagent packs.
- At the end of the lot calibration interval, for a specified lot of calibrated reagent on the system.
- At the end of the pack calibration interval, for calibrated reagent packs on the system.
- When indicated by quality control results.
- After major maintenance or service, if indicated by quality control results.

At the end of the onboard stability interval, replace the reagent pack on the system with a new reagent pack. Recalibration is not required, unless the lot calibration interval is exceeded.

| Stability Interval | Days |
|---|---|
| Lot Calibration | 63 |
| Pack Calibration | 63 |
| Reagent Onboard Stability | 63 |

For information about lot calibration and pack calibration intervals, refer to the online help.

Follow government regulations or accreditation requirements for calibration frequency. Individual laboratory quality control programs and procedures may require more frequent calibration.

### Preparing the Calibrators

Prepare calibrators using the following steps:

1. Add 2.0 mL of special reagent water into each vial using a precision pipet. Replace cap.

   **Note** For information about special reagent water requirements, refer to the online help.

2. Let the vials stand for 15–20 minutes at room temperature to allow the lyophilized material to dissolve.
3. Gently mix and invert the vials to ensure homogeneity of the material.

### Calibration Procedure

The required sample volume for testing depends on several factors. For information about sample volume requirements, refer to the online help.

Use the following lot-specific materials to perform calibration:

- For the master curve and assay test definitions, refer to the lot-specific master curve and test definition sheet MC TDEF provided with the assay reagents.
- Calibrators provided in an assay kit must only be used with reagents from that assay kit lot. Do not use calibrators from one assay kit with reagents from a different assay kit lot.
- For the calibrator definitions, refer to the lot-specific value sheet CAL LOT VAL provided with the calibrator materials.
- Generate lot-specific barcode labels to use with the calibrator samples.

For instructions about how to perform the calibration procedure, refer to the online help.

## Performing Quality Control

For quality control of the Atellica IM TSH3-UL assay, use an appropriate quality control material of known analyte concentration with at least 2 levels at least once during each day that samples are analyzed. Use the quality control material in accordance with the quality control instructions for use.

A satisfactory level of performance is achieved when the analyte values obtained are within the expected control interval for the system or within your interval, as determined by an appropriate internal laboratory quality control scheme. Follow your laboratory's quality control procedures if the results obtained do not fall within the acceptable limits. For information about entering quality control definitions, refer to the online help.

Follow government regulations or accreditation requirements for quality control frequency. Individual laboratory quality control programs and procedures may require more frequent quality control testing.

Test quality control samples after a successful calibration.

### Taking Corrective Action

If the quality control results do not fall within the assigned values, do not report results. Perform corrective actions in accordance with established laboratory protocol. For suggested protocol, refer to the online help.

# Results

## Calculation of Results

The system determines the result using the calculation scheme described in the online help. The system reports results in µIU/mL (common units) or mIU/L (SI units), depending on the units defined when setting up the assay.

Conversion formula: 1 µIU/mL (common units) = 1 mIU/L (SI units)

For information about results outside the specified measuring interval, refer to *Measuring Interval*.

### Interpretation of Results

Results of this assay should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

## Limitations

The following information pertains to limitations of the assay:

- This assay has not been validated for testing samples from newborns.
- Patient samples may contain heterophilic antibodies that could react in immunoassays to give falsely elevated or depressed results. This assay is designed to minimize interference from heterophilic antibodies.[9,10]
- Do not use samples that contain fluorescein. Fluorescein levels > 0.24 µg/mL may decrease results in this assay. Evidence suggests that patients undergoing retinal fluorescein angiography can retain amounts of fluorescein in the body for up to 48–72 hours post-treatment.

  In the cases of patients with renal insufficiency, including many diabetics, retention could be much longer. Such samples can produce falsely depressed values when tested with this assay, and should not be tested. Testing of samples spiked with a theoretical maximum level of fluorescein (250 µg/mL) used in these patients have resulted in TSH levels < 0.06 µIU/mL instead of the true value of 27.99 µIU/mL.[11]
- As with any immuno-recognition measurement of a peptide, extremely rare genetic variants may exhibit varying degrees of detection.[12]

## Expected Values

The reagent formulations used on the Atellica IM Analyzer are the same as those used on the ADVIA Centaur® system. Expected values were established using the ADVIA Centaur system and confirmed by assay comparison. Refer to *Assay Comparison*.

A reference interval for healthy (euthyroid) adults was established on the ADVIA Centaur system in accordance with CLSI guideline C28-A2[13], and verified on the Atellica IM Analyzer in accordance with CLSI guideline EP28-A3c.[14] Samples were assayed for TSH, $FT_3$, and $FT_4$ and considered normal if their values were within acceptable ranges. Samples were also screened for the presence of thyroid autoantibodies.[15] The reference interval was determined by calculating the 2.5th and 97.5th percentiles of the distribution of values.

| Group | Number of Samples | Reference Interval µIU/mL (mIU/L) |
|---|---|---|
| Euthyroid Adults | 229 | 0.55–4.78 |

Reference intervals for the pediatric population (infants, children, and adolescents) were established in accordance with the CLSI guideline EP28-A3c.[14] Samples were collected prospectively from apparently healthy (euthyroid) pediatric subjects, using predefined inclusion criteria.

A non-parametric approach was used to establish the reference intervals for children and adolescents where the 2.5th and 97.5th percentiles of the distribution of values were calculated. For the infant population, the reference interval was calculated using an approach to accommodate the smaller sample size.[16]

| Group | Number of Samples | Reference Interval µIU/mL (mIU/L) |
|---|---|---|
| Infants[a] (1–23 months) | 94 | 0.87–6.15 |
| Children (2–12 years) | 198 | 0.67–4.16 |
| Adolescents (13–20 years) | 150 | 0.48–4.17 |

[a] The upper limit (97.5th percentile) of the infant reference interval was determined to be 6.15 µIU/mL (mIU/L). Data from this infant population (n = 94) have demonstrated a highly skewed distribution to the right. Therefore, the estimate of the upper limit of the reference interval has some uncertainty with a 90% probability that the upper limit of the reference interval can be from 5.32–6.98 µIU/mL (mIU/L).

As with all *in vitro* diagnostic assays, each laboratory should determine its own reference interval for the diagnostic evaluation of patient results.[14] Consider these values as guidance only.

# Performance Characteristics

The reagent formulations used on the Atellica IM Analyzer are the same as those used on the ADVIA Centaur system. Some performance characteristics for the Atellica IM assay were established using the ADVIA Centaur system.

## Measuring Interval

The Atellica IM TSH3-UL assay provides results from 0.008–150.000 µIU/mL (mIU/L). The lower end of the measuring interval is defined by the design requirement for the LoQ. Report results below the measuring interval as < 0.008 µIU/mL (mIU/L).

## Specificity

Specificity of the Atellica IM TSH3-Ultra assay with hCG, FSH, and LH was determined by adding these hormones to human samples containing TSH. Cross-reactivity was shown to be non-detectable for hCG, FSH, and LH tested at 200,000 µIU/mL (mIU/L), 1500 µIU/mL (mIU/L), and 600 µIU/mL (mIU/L), respectively.

Interference testing was performed in accordance wtih CLSI Document EP07-A2[17] using the Atellica IM Analyzer.

## Detection Capability

Detection capability was determined in accordance with CLSI Document EP17-A2.[18] The assay is designed to have a limit of blank (LoB) ≤ 0.004 µIU/mL (mIU/L), a limit of detection (LoD) ≤ 0.008 µIU/mL (mIU/L), and a limit of quantitation (LoQ) ≤ 0.008 µIU/mL (mIU/L).

Representative detection capability data are shown below. Assay results obtained at individual laboratories may vary from the data presented.

The LoB corresponds to the highest measurement result that is likely to be observed for a blank sample. The LoB of the Atellica IM TSH3-UL assay is 0.003 µIU/mL (mIU/L).

The LoD corresponds to the lowest concentration of TSH that can be detected with a probability of 95%. The LoD for the Atellica IM TSH3-UL assay is 0.007 µIU/mL (mIU/L), and was determined using 280 determinations, with 120 blank and 160 low-level replicates, and an LoB of 0.003 µIU/mL (mIU/L).

The LoQ corresponds to the lowest amount of Atellica IM TSH3-UL in a sample at which the repeatability is ≤ 20%. The LoQ of the TSH3-UL assay is 0.007 µIU/mL (mIU/L), and was determined using multiple patient samples in the interval 0.001–0.015 µIU/mL (mIU/L). All samples were assayed in duplicate in each of 2 runs using 3 reagent lots, over a period of 20 days.

## Precision

Precision was determined in accordance with CLSI Document EP05-A3.[19] Samples were assayed on an Atellica IM Analyzer in duplicate in 2 runs per day for 20 days. The assay was designed to have within-laboratory precision of ≤ 0.0032 µIU/mL (mIU/L) SD for samples < 0.020 µIU/mL (mIU/L), ≤ 16% CV for samples from 0.020–0.299 µIU/mL (mIU/L), ≤ 8% CV for samples from 0.300–90.000 µIU/mL (mIU/L), and ≤ 10% CV for samples > 90.000 µIU/mL (mIU/L) TSH. The following results were obtained:

| | | | Repeatability | | Within-Laboratory Precision | |
|---|---|---|---|---|---|---|
| Sample Type | N[a] | Mean µIU/mL (mIU/L) | SD[b] µIU/mL (mIU/L) | CV[c] (%) | SD µIU/mL (mIU/L) | CV (%) |
| Serum A | 80 | 0.019 | 0.001 | N/A[d] | 0.002 | N/A |
| Serum B | 80 | 0.157 | 0.003 | 2.1 | 0.006 | 3.7 |
| Serum C | 80 | 0.972 | 0.012 | 1.2 | 0.029 | 2.9 |
| Serum D | 80 | 8.995 | 0.134 | 1.5 | 0.302 | 3.4 |
| Serum E | 80 | 54.319 | 1.376 | 2.5 | 1.902 | 3.5 |
| Serum F | 80 | 118.735 | 2.477 | 2.1 | 3.897 | 3.3 |
| EDTA Plasma A | 80 | 1.856 | 0.066 | 3.6 | 0.084 | 4.5 |
| EDTA Plasma B | 80 | 38.941 | 1.068 | 2.7 | 1.673 | 4.3 |
| EDTA Plasma C | 80 | 87.724 | 2.273 | 2.6 | 3.317 | 3.8 |
| Heparin Plasma A | 80 | 1.435 | 0.021 | 1.5 | 0.037 | 2.6 |
| Heparin Plasma B | 80 | 38.600 | 0.564 | 1.5 | 1.022 | 2.6 |
| Heparin Plasma C | 80 | 102.047 | 2.010 | 2.0 | 3.491 | 3.4 |
| Control 1 | 80 | 0.468 | 0.009 | 2.0 | 0.014 | 3.1 |
| Control 2 | 80 | 5.349 | 0.100 | 1.9 | 0.147 | 2.7 |
| Control 3 | 80 | 31.908 | 0.739 | 2.3 | 0.997 | 3.1 |

[a] Number of samples tested.
[b] Standard deviation.
[c] Coefficient of variation.
[d] Not applicable.

## Assay Comparison

The Atellica IM TSH3-UL assay is designed to have a correlation coefficient of ≥ 0.95 and a slope of 1.0 ± 0.1 compared to the ADVIA Centaur TSH3-UL assay. Assay comparison was determined using the Passing-Bablok regression model in accordance with CLSI Document EP09-A3.[20] The following results were obtained:

| Specimen | Comparative Assay (x) | Regression Equation | Sample Interval | N[a] | r[b] |
|---|---|---|---|---|---|
| Serum | ADVIA Centaur TSH3-UL | y = 1.05x + 0.001 µIU/mL (mIU/L) | 0.010–132.105 µIU/mL (mIU/L) | 109 | 1.000 |

[a] Number of samples tested.
[b] Correlation coefficient.

Agreement of the assays may vary depending on the study design, comparative assay, and sample population used. Assay results obtained at individual laboratories may vary from the data presented.

## Specimen Equivalency

Specimen equivalency was determined using the Passing-Bablok regression model in accordance with CLSI Document EP09-A3.[20] The following results were obtained:

| Specimen (y) | Reference Specimen (x) | Regression Equation | Sample Interval | N[a] | r[b] |
|---|---|---|---|---|---|
| Lithium heparin | Serum | y = 0.95x - 0.019 µIU/mL (mIU/L) | 0.18–126.08 µIU/mL (mIU/L) | 64 | 1.00 |
| EDTA plasma | Serum | y = 0.94x + 0.007 µIU/mL (mIU/L) | 0.18–126.08 µIU/mL (mIU/L) | 64 | 1.00 |

[a] Number of samples tested.
[b] Correlation coefficient.

Agreement of the specimen types may vary depending on the study design and sample population used. Assay results obtained at individual laboratories may vary from the data presented.

Results were established using the Atellica IM Analyzer.

## Interferences

Interference testing was performed in accordance with CLSI Document EP07-A2.[17]

### Hemolysis, Icterus, and Lipemia (HIL)

| Substance | Substance Test Concentration Common Units (SI Units) | Analyte Concentration µIU/mL (mIU/L) | Percent Bias |
|---|---|---|---|
| Hemoglobin | 500 mg/dL (0.31 mmol/L) | 0.839 | -2 |
| | 500 mg/dL (0.31 mmol/L) | 8.752 | 3 |
| Bilirubin, conjugated | 40 mg/dL (681 µmol/L) | 0.873 | -4 |
| | 40 mg/dL (681 µmol/L) | 9.500 | -4 |
| Bilirubin, unconjugated | 40 mg/dL (681 µmol/L) | 0.875 | -2 |
| | 40 mg/dL (681 µmol/L) | 9.214 | -1 |

| Substance | Substance Test Concentration Common Units (SI Units) | Analyte Concentration µIU/mL (mIU/L) | Percent Bias |
|---|---|---|---|
| Lipemia (Intralipid®) | 1000 mg/dL (11.3 mmol/L) | 0.839 | -0.2 |
| | 1000 mg/dL (11.3 mmol/L) | 8.851 | 0.4 |

Results were established using the Atellica IM Analyzer. Assay results obtained at individual laboratories may vary from the data presented.

### High-Dose Hook Effect

High TSH concentrations can cause a paradoxical decrease in the RLUs (high-dose hook effect). In this assay, patient samples with TSH concentrations as high as 3000 µIU/mL (mIU/L) will report > 150.000 µIU/mL (mIU/L). Results were established using the Atellica IM Analyzer.

### Standardization

The Atellica IM TSH3-UL assay standardization is traceable to the World Health Organization (WHO) 3rd International Standard for human TSH (IRP 81/565). Assigned values for calibrators are traceable to this standardization.

## Technical Assistance

For customer support, contact your local technical support provider or distributor.

siemens.com/healthineers

## References


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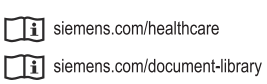
## Definition of Symbols

The following symbols may appear on the product labeling:

| Symbol | Symbol Title and Description |
|---|---|
|  | Consult instructions for use |
|  | Version of instructions for use |
|  | Internet URL address to access the electronic instructions for use |
| Rev. REVISION | Revision |
|  | Caution<br>Consult instructions for use or accompanying documents for cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device. |
|  | Biological risks<br>Potential biological risks are associated with the medical device. |

| Symbol | Symbol Title and Description |
|---|---|
|  | Corrosive |
|  | Dangerous to environment |
|  | Irritant<br>Oral, dermal, or inhalation hazard |
|  | Inhalation hazard<br>Respiratory or internal health |
|  | Flammable<br>Flammable to extremely flammable |
|  | Oxidizing |
|  | Explosive |
|  | Toxic |
|  | Compressed gas |
|  | Keep away from sunlight<br>Prevent exposure to sunlight and heat. |
|  | Up<br>Store in an upright position. |
|  | Do not freeze |
|  | Temperature limit<br>Upper and lower limits of temperature indicators are adjacent to the upper and lower horizontal lines. |
|  | Handheld barcode scanner |
|  | *In vitro* diagnostic medical device |
|  | Contains sufficient for <n> tests<br>Total number of IVD tests the system can perform with the IVD kit reagents appears adjacent to the symbol. |

| Symbol | Symbol Title and Description |
|---|---|
| **RxOnly** | Prescription device (US only)<br>Applies only to United States-registered IVD assays.<br>CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare professional. |
|  | Mixing of substances<br>Mix product before use. |
|  | Reconstitute and mix lyophilized product before use. |
|  | Target |
|  | Interval |
|  | Legal Manufacturer |
| EC REP | Authorized Representative in the European Community |
|  | Use-by date<br>Use by the designated date. |
| LOT | Batch code |
| REF | Catalog number |
|  | Recycle |
|  | Printed with soy ink |
|  | CE Mark |
|  | CE Mark with notified body ID number<br>Notified body ID number can vary. |
| YYYY-MM-DD | Date format (year-month-day) |
| CHECKSUM | Variable hexadecimal number that ensures the Master Curve and Calibrator definition values entered are valid. |
| UNITS C | Common Units |
| UNITS SI | International System of Units |
| MATERIAL | Material |
| MATERIAL ID | Unique material identification number |

| Symbol | Symbol Title and Description |
|---|---|
| CONTROL NAME | Name of control |
| CONTROL TYPE | Type of control |

## Legal Information



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Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591
USA
siemens.com/healthineers

**Siemens Healthineers Headquarters**
Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen
Germany
Phone: +49 9131 84-0
siemens.com/healthineers