Abbott

Declaration of Conformity

Certificate Identification:	7K62
Legal Manufacturer's Name:	Abbott Ireland Diagnostics Division
Legal Manufacturer's Address:	Lisnamuck, Longford
	Co. Longford
	Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K62-20 7K62-25 7K62-30 7K62-35	54386	ARCHITECT TSH Reagent Kit	**Self-declared**
7K62-01	38272	ARCHITECT TSH Calibrators	**Self-declared**
7K62-10	38271	ARCHITECT TSH Controls	**Self-declared**

Authorized European Representative (Name and Address)	N/A
Storage of site technical documentation (Name and Address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland. Department: Regulatory Affairs
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:	Kevin Callaghan	Signature:	Lorraine Whitney
Full Name:	Kevin Callaghan	Full Name:	Lorraine Whitney
Position:	Quality Manager	Position:	Senior Manager Regulatory Affairs
Date of Approval:	25 May 2017	Date of Approval:	25 May 2017
Date Issued:	25 May 2017	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland
Supersedes:	22 April 2014	Effective (Date or Lot Number):	2017

S.R.L. "GBG-MLD" No.1

ABBOTT

Declaration of Conformity

Certificate Identification:	7K63
Legal Manufacturer's Name:	Abbott Ireland Diagnostics Division
Legal Manufacturer's Address:	Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K63-27 7K63-32 7K63-37	54417	ARCHITECT Free T3 Reagent Kit	**Self-declared**
7K63-02	38261	ARCHITECT Free T3 Calibrators	**Self-declared**
7K63-12	54418	ARCHITECT Free T3 Controls	**Self-declared**

Authorized European Representative (name and address)	N/A
Storage of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:		Signature:	
Full Name:	Kevin Callaghan	Full Name:	Lorraine Whitney
Position:	Quality Manager	Position:	Senior Manager Regulatory Affairs
Date of Approval:	18 April 2017	Date of Approval:	18 April 2017
Date Issued:	24 April 2017	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland
Supersedes:	n/a	Effective (Date or Lot Number):	24 April 2017

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "GBG-MLD" REPUBLICA MOLDOVA, MUN. CHIȘINĂU

Abbott

Declaration of Conformity

Certificate Identification:	7K65-22/-24/-27/-29/-32/-34/-35/-39, 7K65-02, 7K65-10
Legal Manufacturer's Name:	Abbott Ireland Diagnostics Division
Legal Manufacturer's Address:	Lisnamuck, Longford
	Co. Longford
	Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K65-22 7K65-24 7K65-27 7K65-29 7K65-32 7K65-34 7K65-35 7K65-39	54413	ARCHITECT Free T4 Reagent Kit	**Self-declared**
7K65-02	38259	ARCHITECT Free T4 Calibrators	**Self-declared**
7K65-10	38258	ARCHITECT Free T4 Controls	**Self-declared**

Authorized European Representative (Name and Address)	N/A
Storage of site technical documentation (Name and Address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:	Siobhan Wright	Signature:	Lorraine Whitney
Full Name:	Siobhan Wright	Full Name:	Lorraine Whitney
Position:	Quality Manager	Position:	Senior Manager Regulatory Affairs
Date of Approval:	29-OCT-15	Date of Approval:	30 OCT 15
Date Issued:	30 OCT 15	Place Issued:	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland
Supersedes:	22 APRIL 2014	Effective (Date or Lot Number):	30 OCT 15

ABBOTT

Declaration of Conformity

Certificate Identification:	S1330
Legal Manufacturer's Name:	Abbott Ireland Diagnostics Division
Legal Manufacturer's Address:	Lisnamuck, Longford, Co. Longford, Ireland.

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
7K64-20 7K64-25 7K64-30	30312	Architect Total T_3 Reagent Kit	Self-declared
7K64-01	30504	Architect Total T_3 Calibrators	Self-declared
7K64-50	N/A	Architect Total T_3 Manual Diluent	Self-declared

Authorized European Representative (name and address)	N/A
Storage of technical documentation (name and address)	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC and transposed Irish Regulation S.I. No 304 of 2001 and to the EC Directive 98/79/EC as it is transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:	Mark A Duffy MARTIN DUFFY	Signature:	Lorraine Whitney
Full Name (printed):	Stefan Molitor	Full Name (printed):	Lorraine Whitney
Position:	Quality Manager	Position:	Regulatory Affairs Group Leader
Date:	05 April '06	Date:	05 April 2006
		Date Issued:	06 April 2006
		Place Issued	Abbott Ireland Diagnostics Division, Lisnamuck, Longford, Co. Longford, Ireland.
		Supersedes:	N/A
		Effective (Lot number or date)	06 April 2006

Abbott

Declaration of Conformity

Certificate Identification: 02K47 LC IRIS V2
Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
2K47-20 2K47-22 2K47-25 2K47-27	58729	ARCHITECT Anti-TPO Reagent Kit	Self-declared
2K47-01	55210	ARCHITECT Anti-TPO Calibrators	Self-declared
2K47-10	55211	ARCHITECT Anti-TPO Controls	Self-declared

Authorized European Representative (Name and Address)	Abbott GmbH & Co. KG Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Fisher Diagnostics a division of Fisher Scientific Company LLC a part of Thermo Fisher Scientific Inc. 8365 Valley Pike, Middleton, VA 22645-1905 USA
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.
This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: William H Phillips
Full Name: William H Phillips
Position: Quality Manager
Date of Approval: 12/09/2014
Date Issued: 12/15/2014
Supersedes: 28 July 2006

Signature: Mary Ann Muszynski
Full Name: Mary Ann Muszynski
Position: Regulatory Affairs Manager
Date of Approval: 12/11/2014
Place Issued: Abbott Laboratories Diagnostics Div. Abbott Park, IL 60064 USA
Effective (Date or Lot Number): 12/15/2014

TECHNOPATH

DECLARATION OF CONFORMITY

Manufacturer
Techno-path Manufacturing Ltd.
Fort Henry Business Park,
Ballina,
Co. Tipperary,
Ireland

Product(s):

Product Name	Catalogue Number
Multichem IA Plus	IA310X
Multichem IA Plus	IA311X
Multichem IA Plus	IA312X
Multichem IA Plus	IA313X
Multichem IA Plus	IA314X
Multichem IA Plus	05P76-10
Multichem IA Plus	IA310A
Multichem IA Plus	IA311A
Multichem IA Plus	IA312A
Multichem IA Plus	IA313A

GMDN:	47869
Classification:	Annex II List B
Conformity Route:	Annex IV
Quality Management System:	EN ISO 13485:2012 / ISO 13485:2003
QMS/CE Certification No.:	LRQ 4008261/B
Issued By:	Lloyds Register LRQA, 71 Fenchurch Street, London EC3M 4BS United Kingdom
Notified Body Number:	0088

Standards Applied: See attached list of standards for which documented evidence of compliance can be provided.

Techno-path Manufacturing Ltd. hereby declares that the product(s) specified above comply with the requirements listed in European Union In-vitro Diagnostic Medical Device Directive 98/79/EC.

Signed for and on behalf of Techno-path Manufacturing Ltd.,

Bernd Hass, Head of Quality and Regulatory Affairs
Techno-path Manufacturing Ltd.

Date 24-Jan-2014

TECHNOPATH

STANDARDS USED IN FULL OR PART FOR CE MARKING AS PER IVDD 98/79/EC

Standard	Title
EN ISO 15223-1:2012	Symbols for use in the labelling of medical devices
ISO 13485:2012 + AC:2012	Medical devices – Quality management systems – Requirements for regulatory purposes
EN 13612:2002 + AC:2002	Performance evaluation of in vitro diagnostic medical devices
EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN 13975:2003	Sampling procedures used for acceptance testing of in in vitro diagnostic medical devices – statistical aspects
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN ISO 18113-1:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2011	In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 2: In vitro diagnostic reagents for professional use
EN 13640:2002	Stability Testing of In vitro diagnostic reagents

Abbott

Declaration of Conformity

Certificate Identification: ARCHITECT Solutions
Legal Manufacturer's Name: Abbott Ireland Diagnostics Division
Legal Manufacturer's Address: Finisklin Business Park
Sligo
Ireland

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
1L56-40	Not Available	ARCHITECT Probe Conditioning Solution	Self-declared
6C54-58	Not Available	ARCHITECT Concentrated Wash Buffer	Self-declared
6C54-82	Not Available	ARCHITECT Concentrated Wash Buffer	Self-declared
6C54-88	Not Available	ARCHITECT ARM Concentrated Wash Buffer	Self-declared
6C55-60	Not Available	ARCHITECT Trigger Solution	Self-declared
6C55-82	Not Available	ARCHITECT Trigger Solution	Self-declared
6E23-65	Not Available	ARCHITECT Pre-Trigger Solution	Self-declared
6E23-82	Not Available	ARCHITECT Pre-Trigger Solution	Self-declared
7D82-50	Not Available	ARCHITECT Multi-Assay Manual Diluent	Self-declared

Authorized European Representative (Name and Address)	N/A
Storage site of technical documentation (Name and Address)	Abbott Ireland Diagnostics Division, Finisklin Business Park, Sligo, County Sligo, Ireland. Department: Regulatory Affairs.
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature: [signature]
Full Name: Niall Plunkett
Position: Quality Manager
Date of Approval: 07 Jul 14
Date Issued: 07 JUL 14
Supersedes: 15 Jun 2012

Signature: Lorraine Whitney
Full Name: Lorraine Whitney
Position: Senior Manager Regulatory Affairs
Date of Approval: 04 July 2014
Place Issued: AIDD Sligo
Effective (Date or Lot Number): 07 JUL 14

Abbott

Declaration of Conformity

Certificate Identification:	ARCH Sys Acc LC	IRIS V3
Legal Manufacturer's Name:	Abbott Laboratories	
Legal Manufacturer's Address:	Diagnostics Division	
	Abbott Park, IL 60064 USA	

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
4D18-03	NA	ARCHITECT Septum	Self-declared
4D19-01	NA	ARCHITECT Replacement Caps	Self-declared
7C14-01	NA	ARCHITECT Sample Cups	Self-declared
7C15-02	NA	ARCHITECT Reaction Vessels	Self-declared
7C15-03	NA	ARCHITECT Reaction Vessels	Self-declared

Authorized European Representative (name and address)	Abbott GmbH & Co. KG Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 USA
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.
This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature		Signature	
Full Name:	_Lauren Sieber_	Full Name:	_Deborah Hinkley_
Position:	Product Quality Assurance Manager	Position	Regulatory Affairs Director
Date of Approval:	5/28/2015	Date of Approval:	5/29/2015
Date Issued:	06/02/2015	Place Issued:	Abbott Laboratories Diagnostics Division Abbott Park, IL 60064 USA
Supersedes	June 13, 2013	Effective (Date or Lot Number):	06/02/2015

SOCIETATEA EU "GBG-MED"

ARCHITECT TSH Calibrators

REF 7K62-01

en
TSH
7K62
G6-2727 / R04
S7K620

Read Highlighted Changes: Revised November 2015.

INTENDED USE

The ARCHITECT TSH Calibrators are for the calibration of the ARCHITECT iSystem when used for the quantitative determination of human Thyroid Stimulating Hormone (TSH) in human serum and plasma. Refer to the ARCHITECT assay-specific reagent package insert for additional information.

CONTENTS

2 Bottles (4 mL each) of ARCHITECT TSH Calibrators. Calibrator 1 contains TRIS buffer with protein (bovine) stabilizers; Calibrator 2 contains TSH (recombinant) in TRIS buffer with protein (bovine) stabilizers. Preservative: sodium azide.

The calibrators yield the following concentrations:

	TSH Concentration	
Calibrators	(µIU/mL)	(mIU/L)
CAL 1	0	0
CAL 2	40	40

STANDARDIZATION

The calibrators are manufactured by addition of Recombinant Human TSH of known concentration to obtain a target concentration. The concentration is referenced against WHO TSH 80/558.

PRECAUTIONS

- IVD
- For *In Vitro* Diagnostic Use

The following warnings and precautions apply to: CAL 1 / CAL 2	
Contains sodium azide.	
EUH032	Contact with acids liberates very toxic gas.
P501	Dispose of contents / container in accordance with local regulations.

Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

STORAGE

- Calibrators are stable until the expiration date when stored and handled as directed.
- Do not use past expiration date.
- 2°C – 8°C

Key to Symbols

	Consult instructions for use
	Manufacturer
	Temperature limitation
	Use by/Expiration date
CAL 1	Calibrator 1
CAL 2	Calibrator 2
CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
DISTRIBUTED IN THE USA BY	Distributed in the USA by
INFORMATION FOR USA ONLY	Information needed for United States of America only
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
PRODUCT OF IRELAND	Product of Ireland
REF	List Number

Abbott Ireland
Diagnostics Division
Lisnamuck, Longford
Co. Longford
Ireland
+353-43-3331000

DISTRIBUTED IN THE USA BY
Abbott Laboratories
Abbott Park, IL 60064 USA

Customer Service: Contact your local representative or find country-specific contact information on www.abbottdiagnostics.com

Revised November 2015.

Abbott

ARCHITECT TSH Controls

REF 7K62-10

en
TSH
7K62
G6-2728 / R04
C7K620

Read Highlighted Changes: Revised November 2015.

INTENDED USE

The ARCHITECT TSH Controls are for the verification of the accuracy and precision of the ARCHITECT iSystem when used for the quantitative determination of human Thyroid Stimulating Hormone (TSH) in human serum and plasma. Refer to the ARCHITECT assay-specific reagent package insert for additional information.

CONTENTS

3 Bottles (8 mL each) of ARCHITECT TSH Controls. Low Control, Medium Control, High Control contain TSH (recombinant) prepared in TRIS buffer with protein (bovine) stabilizers. Preservative: sodium azide.

The following concentration ranges may be used for individual replicate control specifications on the ARCHITECT iSystem:

Control	Target Concentration (µIU/mL)	Range (µIU/mL)	Target Concentration (mIU/L)	Range (mIU/L)
CONTROL L	0.1	0.065 - 0.135	0.1	0.065 - 0.135
CONTROL M	6	3.9 - 8.1	6	3.9 - 8.1
CONTROL H	30	19.5 - 40.5	30	19.5 - 40.5

Each laboratory should establish its own concentration ranges for new control lots at each control level. This can be accomplished by assaying a minimum of 20 replicates over several (3-5) days. Sources of variation that can be expected should be included in this study in order to be representative of future system performance. These may include:

- Multiple stored calibrations
- Multiple reagent lots
- Multiple calibrator lots
- Multiple processing modules
- Data points collected at different times of the day

These results should be applied to your laboratory's quality control practices.

STANDARDIZATION

The controls are manufactured by addition of Recombinant Human TSH of known concentration to obtain a target concentration. This internally assigned concentration is established using calibration values referenced against WHO TSH 80/558.

PRECAUTIONS

- IVD
- For *In Vitro* Diagnostic Use

The following warnings and precautions apply to: CONTROL L, CONTROL M, CONTROL H	
Contains sodium azide.	
EUH032	Contact with acids liberates very toxic gas.
P501	Dispose of contents / container in accordance with local regulations.

Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

STORAGE

- Controls are stable until the expiration date when stored and handled as directed.
- Do not use past expiration date.
- 2°C – 8°C

Key to Symbols

	Consult instructions for use
	Manufacturer
	Temperature limitation
	Use by/Expiration date
CONC	Concentration
CONTAINS: AZIDE	Contains Sodium Azide. Contact with acids liberates very toxic gas.
CONTROL L	Control Low, Medium, High (L,M,H)
DISTRIBUTED IN THE USA BY	Distributed in the USA by
INFORMATION FOR USA ONLY	Information needed for United States of America only
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
PRODUCT OF IRELAND	Product of Ireland
RANGE	Range
REF	List Number

Abbott Ireland
Diagnostics Division
Lisnamuck, Longford
Co. Longford
Ireland
+353-43-3331000

DISTRIBUTED IN THE USA BY
Abbott Laboratories
Abbott Park, IL 60064 USA

CE

Customer Service: Contact your local representative or find country-specific contact information on www.abbottdiagnostics.com

Revised November 2015.

Abbott

ARCHITECT TSH

REF 7K62-25
REF 7K62-20
REF 7K62-35
REF 7K62-30

en
TSH
7K62
G6-2729/R06
B7K620

Read Highlighted Changes: Revised November 2015.

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

NAME

ARCHITECT TSH

INTENDED USE

The ARCHITECT TSH assay is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of human Thyroid Stimulating Hormone (TSH) in human serum and plasma.

SUMMARY AND EXPLANATION OF THE TEST

Human Thyroid Stimulating Hormone (TSH) or thyrotropin is a glycoprotein with a molecular weight of approximately 28,000 daltons, synthesized by the basophilic cells (thyrotropes) of the anterior pituitary.[1] TSH is composed of two non-covalently linked subunits designated alpha and beta. Although the alpha subunit of TSH is common to the luteinizing hormone (LH), follicle stimulating hormone (FSH) and human chorionic gonadotropin (hCG), the beta subunits of these glycoproteins are hormone specific and confer biological as well as immunological specificity. Both alpha and beta subunits are required for biological activity.[1] TSH stimulates the production and secretion of the metabolically active thyroid hormones, thyroxine (T_4) and triiodothyronine (T_3), by interacting with a specific receptor on the thyroid cell surface.[2] T_3 and T_4 are responsible for regulating diverse biochemical processes throughout the body which are essential for normal development and metabolic and neural activity.

The synthesis and secretion of TSH is stimulated by thyrotropin releasing hormone (TRH), the hypothalamic tripeptide, in response to low levels of circulating thyroid hormones.[3, 4] Elevated levels of T_3 and T_4 suppress the production of TSH via a classic negative feedback mechanism. Other evidence also indicates that somatostatin and dopamine exert inhibitory control over TSH release, suggesting that the hypothalamus may provide both inhibitory and stimulatory influence on pituitary TSH production.[5] Failure at any level of regulation of the hypothalamic-pituitary-thyroid axis will result in either underproduction (hypothyroidism) or overproduction (hyperthyroidism) of T_4 and/or T_3.

In cases of primary hypothyroidism, T_3 and T_4 levels are low and TSH levels are significantly elevated.[6] In the case of pituitary dysfunction, either due to intrinsic hypothalamic or pituitary disease; i.e., central hypothyroidism, normal or marginally elevated basal TSH levels are often seen despite significant reduction in T_4 and/or T_3 levels. These inappropriate TSH values are due to a reduction in TSH bioactivity which is frequently observed in such cases. Routine TRH stimulation is advised to confirm the diagnosis in such cases. Secondary hypothyroidism typically results in an impaired TSH response to TRH, while in tertiary hypothyroidism the TSH response to TRH may be normal, prolonged or exaggerated.[7-9]

Primary hyperthyroidism (e.g., Grave's Disease, nodular goiter) is associated with high levels of thyroid hormones and depressed or undetectable levels of TSH.[10] The TRH stimulation test has been used in diagnosis of hyperthyroidism. Hyperthyroid patients show a subnormal response to the TRH test.[11] In addition, large doses of glucocorticoids, somatostatin, dopamine and replacement doses of thyroid hormones reduce or totally blunt the TSH response to TRH.[11, 12]

Earlier assays for serum TSH lacked the sensitivity to be used as a primary test of thyroid function.[13] Sensitive TSH assays now available, with increased ability to clearly distinguish between euthyroid and hyperthyroid populations, are changing thyroid function testing. Analytical sensitivity, as a means of assessing low concentration accuracy, is being replaced by functional sensitivity.[14] The American Thyroid Association has formally recommended the use of functional sensitivity as the means to quantify the sensitivity of TSH assays,[15] although analytical sensitivity is still widely used. Third generation TSH assays exhibit 20% interassay CVs at < 0.02 µIU/mL and are useful in the discrimination of patients with true hyperthyroidism from those with TSH suppression seen in subclinical hyperthyroidism and some non-thyroidal illnesses.[16] Other thyroid tests (Free T_4 estimate, Total T_4, T-Uptake, and Total T_3) combined with the ability to accurately measure low levels of TSH, improve the efficiency of thyroid diagnosis.[17]

The ARCHITECT TSH assay is used as an aid in the assessment of thyroid status, diagnosis of thyroid disease, and treatment of thyroid disease.

BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The ARCHITECT TSH assay is a two-step immunoassay to determine the presence of Thyroid Stimulating Hormone (TSH) in human serum and plasma using CMIA technology with flexible assay protocols, referred to as Chemiflex.

1. Sample, anti-β TSH antibody coated paramagnetic microparticles and TSH Assay Diluent are combined. TSH present in the sample binds to the anti-TSH antibody coated microparticles.
2. After washing, anti-α TSH acridinium-labeled conjugate is added to create a reaction mixture.
3. Following another wash cycle, Pre-Trigger and Trigger Solutions are added to the reaction mixture.
4. The resulting chemiluminescent reaction is measured as relative light units (RLUs). There is a direct relationship between the amount of TSH in the sample and the RLUs detected by the ARCHITECT iSystem optics.

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

REAGENTS

Kit Contents

ARCHITECT TSH 7K62

NOTE: Some kit sizes are not available in all countries or for use on all ARCHITECT iSystems. Please contact your local distributor.

REF	7K62-25	7K62-20	7K62-35	7K62-30
Σ	100	400	500	2000
MICROPARTICLES	1 x 6.6 mL	4 x 6.6 mL	1 x 27.0 mL	4 x 27.0 mL
CONJUGATE	1 x 5.9 mL	4 x 5.9 mL	1 x 26.3 mL	4 x 26.3 mL
ASSAY DILUENT	1 x 8.0 mL	4 x 8.0 mL	1 x 40.7 mL	4 x 40.7 mL

MICROPARTICLES Anti-β TSH (mouse, monoclonal) coated Microparticles in TRIS buffer with protein, bovine) stabilizers. Minimum concentration: 0.07% solids. Preservatives, antimicrobial agents.

REF	7K62-25	7K62-20	7K62-35	7K62-30
Σ	100	400	500	2000

CONJUGATE Anti-α TSH (mouse, monoclonal) acridinium-labeled Conjugate in MES buffer with protein (bovine) stabilizers. Minimum concentration: 60 ng/mL. Preservative: antimicrobial agent.

ASSAY DILUENT TSH Assay Diluent in TRIS buffer. Preservative: antimicrobial agents.

Other Reagents

MULTI-ASSAY MANUAL DILUENT 1 x 100 mL ARCHITECT Multi-Assay Manual Diluent, **REF** 7D82-50, containing phosphate buffered saline solution. Preservative: antimicrobial agent.

PRE-TRIGGER SOLUTION ARCHITECT Pre-Trigger Solution containing 1.32% (w/v) hydrogen peroxide.

TRIGGER SOLUTION ARCHITECT Trigger Solution containing 0.35 N sodium hydroxide.

WASH BUFFER ARCHITECT Wash Buffer containing phosphate buffered saline solution. Preservatives: antimicrobial agents.

NOTE: Bottle and volume varies based on order.

Warnings and Precautions

- **IVD**
- For *In Vitro* Diagnostic Use

Safety Precautions

CAUTION: This product requires the handling of human specimens. It is recommended that all human-sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.[16-21]

The following warnings and precautions apply to: **ASSAY DILUENT**	
◇!	
WARNING:	Contains Tris Hydroxymethyl Aminomethane and Tromethamine Hydrochloride.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
Prevention	
P264	Wash hands thoroughly after handling.
P280	Wear protective gloves / protective clothing / eye protection.
P261	Avoid breathing mist / vapors / spray.
P271	Use only outdoors or in a well-ventilated area.
Response	
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice / attention.
P302+P352	IF ON SKIN: Wash with plenty of water.
P332+P313	If skin irritation occurs: Get medical advice / attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P312	Call a POISON CENTER or doctor / physician if you feel unwell.
Storage	
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
Disposal	
P501	Dispose of contents / container in accordance with local regulations.

Safety Data Sheets are available at www.abbottdiagnostics.com or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

Reagent Handling

- Do not use reagent kits beyond the expiration date.
- **Do not pool reagents within a kit or between kits.**
- Before loading the reagent kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that may have settled during shipment. For microparticle mixing instructions, refer to the **PROCEDURE, Assay Procedure** section of this package insert.
- **Septums MUST be used to prevent reagent evaporation and contamination and to ensure reagent integrity. Reliability of assay results cannot be guaranteed if septums are not used according to the instructions in this package insert.**
  - To avoid contamination, wear clean gloves when placing a septum on an uncapped reagent bottle.
  - Once a septum has been placed on an open reagent bottle, **do not invert the bottle** as this will result in reagent leakage and may compromise assay results.
  - Over time, residual liquids may dry on the septum surface. These are typically dried salts and have no effect on assay efficacy.

For a detailed discussion of handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Reagent Storage

	Storage Temperature	Maximum Storage Time	Additional Storage Instructions
Unopened/ Opened*	2-8°C	Until expiration date	May be used immediately after removal from 2-8°C storage.
On board	System temperature	30 days	Discard after 30 days. For information on tracking onboard time, refer to the ARCHITECT System Operations Manual, Section 5.

* Reagents may be stored on or off the ARCHITECT iSystem. If reagents are removed from the system, store them at 2-8°C (with septums and replacement caps) in an upright position. For reagents stored off the system, it is recommended that they be stored in their original trays and boxes to ensure they remain upright. **If the microparticle bottle does not remain upright (with a septum installed) while in refrigerated storage off the system, the reagent kit must be discarded.** For information on unloading reagents, refer to the ARCHITECT System Operations Manual, Section 5.

Indications of Reagent Deterioration

When a control value is out of the specified range, it may indicate deterioration of the reagents or errors in technique. Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

The ARCHITECT TSH assay file must be installed on the ARCHITECT iSystem from an ARCHITECT iSystem Assay CD-ROM prior to performing the assay.

For detailed information on assay file installation and viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.

For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.

For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.

Alternate Result Units

Edit assay parameter "Result concentration units" to select an alternate unit.

Conversion formula:

(Concentration in Default result unit) x (Conversion factor) = (Concentration in Alternate result unit)

Default result unit	Conversion factor	Alternate result unit
µIU/ mL	1	mIU/L

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

Validated specimen types to be used with this assay:

Specimen Types	Collection Tubes
Human serum	Serum
	Serum separator tubes (SST)
Human plasma	Lithium heparin
	Sodium heparin
	Potassium EDTA

- Other anticoagulants have not been validated for use with the ARCHITECT TSH assay.
- The instrument does not provide the capability to verify specimen type. It is the responsibility of the operator to verify that the correct specimen types are used in the assay.

Specimen Conditions

- **For optimal results, serum and plasma specimens should be free of fibrin, red blood cells, or other particulate matter. Centrifuge specimens containing fibrin, red blood cells, or particulate matter prior to use to ensure consistency in the results.**
- **Ensure that complete clot formation in serum specimens has taken place prior to centrifugation. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy may exhibit increased clotting time. If specimens are centrifuged before a complete clot forms, the presence of fibrin or particulate matter may cause erroneous results. Centrifuge specimens containing fibrin, red blood cells, or particulate matter. Note that interfering levels of fibrin may be present in samples that do not have obvious or visible particulate matter.**
- **If proper specimen collection and preparation cannot be verified, or if samples have been disrupted due to transportation or sample handling, an additional centrifugation step is recommended. Centrifugation conditions should be sufficient to remove particulate matter. Aliquots poured versus pipetted from specimen tube types that do not include serum separators are at higher risk of including particulates and generating depressed results.**
- **Failure to follow these instructions may result in depressed specimen results.**
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.

Preparation for Analysis

- **Follow these package insert instructions as well as the specimen collection tube manufacturer's instructions for specimen collection and preparation for analysis. Refer to the specimen collection tube manufacturer's instructions for centrifugation time and speed.**
- **Insufficient processing of sample, or disruption of the sample during transportation may cause depressed results.**
- Mix thawed specimens thoroughly by low speed vortexing or by inverting 10 times. Visually inspect the specimens. If layering or stratification is observed, continue mixing until specimens are visibly homogeneous.
- Prepare frozen specimens as follows:
  - Frozen specimens must be completely thawed before mixing.
  - Mix thawed specimens thoroughly by low speed vortexing or by inverting 10 times. Visually inspect the specimens. If layering or stratification is observed, continue mixing until specimens are visibly homogeneous. If samples are not mixed thoroughly, inconsistent results may be obtained.
  - Centrifuge mixed specimens as described below.
- To ensure consistency in results, centrifuge specimens before testing if
  - they contain fibrin, red blood cells, or other particulate matter or
  - they were frozen and thawed.
- Inspect all specimens for bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.

Specimen Storage

Specimen Type	Storage Temperature	Maximum Storage Time
Serum/Plasma	2-8°C	≤ 7 days

If testing will be delayed more than 24 hours, remove serum or plasma from the clot, serum separator or red blood cells.

If testing will be delayed more than 7 days, specimens should be frozen at -10°C or colder. Specimens stored frozen at -10°C or colder for 6 months showed no performance difference.

Specimens must be mixed thoroughly after thawing to ensure consistency of the results.

Avoid multiple freeze/thaw cycles.

Specimen Shipping

- Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.
- Do not exceed the storage limitations listed above.

PROCEDURE

Materials Provided

7K62 ARCHITECT TSH Reagent Kit

Materials Required but not Provided

- ARCHITECT TSH Assay file obtained from the ARCHITECT iSystem e-Assay CD-ROM found on www.abbottdiagnostics.com.
- 7K62-01 ARCHITECT TSH Calibrators
- 7K62-10 ARCHITECT TSH Controls
- 7D82-50 ARCHITECT Multi-Assay Manual Diluent
- ARCHITECT Pre-Trigger Solution
- ARCHITECT Trigger Solution
- ARCHITECT Wash Buffer
- ARCHITECT Reaction Vessels
- ARCHITECT Sample Cups
- ARCHITECT Septum
- ARCHITECT Replacement Caps
- Pipettes or pipette tips (optional) to deliver the volumes specified on the patient or control order screen.

For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.

Assay Procedure

- Before loading the reagent kit on the system for the first time, the microparticle bottle requires mixing to resuspend microparticles that may have settled during shipment. After the first time the microparticles have been loaded, no further mixing is required.
  - **Invert the microparticle bottle 30 times.**
  - Visually inspect the bottle to ensure microparticles are resuspended. If microparticles are still adhered to the bottle, continue to invert the bottle until the microparticles have been completely resuspended.
  - **If the microparticles do not resuspend, DO NOT USE. Contact your local Abbott representative.**
  - Once the microparticles have been resuspended, place a septum on the bottle. For instructions about placing septums on bottles, refer to the **Reagent Handling** section of this package insert.
- Load the reagent kit on the ARCHITECT iSystem.
  - Verify that all necessary reagents are present.
  - Ensure that septums are present on all reagent bottles.
- Order calibration, if necessary.
  - For information on ordering calibrations, refer to the ARCHITECT System Operations Manual, Section 6.
- Order tests.
  - For information on ordering patient specimens and controls and for general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.
- Minimum sample cup volume is calculated by the system and printed on the Orderlist report. To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.

  Maximum number of replicates sampled from the same sample cup: 9
  - Priority:

    Sample volume for first test: 200 µL

    Sample volume for each additional test from same sample cup: 150 µL
  - ≤ 3 hours on board:

    Sample volume for first test: 200 µL

    Sample volume for each additional test from same sample cup: 150 µL
  - > 3 hours on board: Additional sample volume is required. Refer to the ARCHITECT System Operations Manual, Section 5 for information on sample evaporation and volumes.
  - If using primary or aliquot tubes, use the sample gauge to ensure sufficient patient specimen is present.
- Prepare ARCHITECT TSH Calibrators and Controls.
  - Mix calibrator(s) and controls by gentle inversion before use.
  - Hold bottles **vertically** and dispense recommended volumes into each respective sample cup.
  - Recommended volumes:

    for each calibrator: 6 drops

    for each control: 4 drops
- Load samples.
  - For information on loading samples, refer to the ARCHITECT System Operations Manual, Section 5.
- Press RUN.
  - For additional information on principles of operation, refer to the ARCHITECT System Operations Manual, Section 3.
  - For optimal performance, it is important to perform routine maintenance as described in the ARCHITECT System Operations Manual, Section 9. Perform maintenance more frequently when required by laboratory procedures.

Specimen Dilution Procedures

Specimens with a TSH value exceeding 100.0000 µIU/mL are flagged with the code ">100.0000" and may be diluted using either the Automated Dilution Protocol or the Manual Dilution Procedure.

Automated Dilution Protocol

The system performs a 1:5 dilution of the specimen and automatically calculates the concentration of the diluted specimen and reports the result.

Manual Dilution Procedure

Suggested dilution: 1:10

It is recommended that dilutions not exceed 1:10.

1. Add 30 µL of the patient specimen to 270 µL of ARCHITECT Multi-Assay Manual Diluent.
2. The operator must enter the dilution factor in the Patient or Control order screen. The system will use this dilution factor to automatically calculate the concentration of the sample before dilution and report the result. The result should be > 0.0100 µIU/mL before the dilution factor is applied.
3. If the operator does not enter the dilution factor, the reported result will be that of the diluted sample. This result should be > 0.0100 µIU/mL before the dilution factor is applied.

For detailed information on ordering dilutions, refer to the ARCHITECT System Operations Manual, Section 5.

Calibration

- Test Calibrators 1 and 2 in duplicate. The calibrators should be priority loaded.

  A single sample of each control level must be tested to evaluate the assay calibration. Ensure that assay control values are within the ranges specified in the respective control package insert.
- Calibration Range: 0.0000 - 100.0000 µIU/mL.
- Once an ARCHITECT TSH calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:
  - A reagent kit with a new lot number is used or
  - Controls are out of range.
- For detailed information on how to perform an assay calibration, refer to the ARCHITECT System Operations Manual, Section 6.

Quality Control Procedures

The recommended control requirement for the ARCHITECT TSH assay is that a single replicate of each control level be tested once every 24 hours each day of use. If the quality control procedures in your laboratory require more frequent use of controls to verify test results, follow your laboratory-specific procedures.

Ensure that assay control values are within the concentration ranges specified in the package insert.

Verification of Assay Claims

For protocols to verify package insert claims, refer to the ARCHITECT System Operations Manual, Appendix B.

The ARCHITECT TSH assay belongs to method group 1.

The lower limit of the dynamic range is defined as the functional sensitivity of the assay.

RESULTS

Calculation

The ARCHITECT TSH assay utilizes a 4 Parameter Logistic Curve fit data reduction method (4PLC, Y-weighted) to generate a calibration curve.

For information on alternate result units, refer to the **INSTRUMENT PROCEDURE, Alternate Result Units** section of this package insert.

Flags

Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the ARCHITECT System Operations Manual, Section 5.

LIMITATIONS OF THE PROCEDURE

- Specimens run on the ARCHITECT TSH assay MUST be processed according to the specimen test tube manufacturer's instruction. Insufficient processing including deviations from recommended clotting times, centrifugation times, centrifugation speed and sample preparation techniques may cause inaccurate results.
- Results should be used in conjunction with other data; e.g., symptoms, results of other tests, and clinical impressions.
- If the TSH results are inconsistent with clinical evidence, additional testing is recommended to confirm the result.
- Suspected hyperthyroidism based on low or undetectable TSH levels should be confirmed with additional thyroid function testing along with other clinical information.
- Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits such as ARCHITECT TSH that employ mouse monoclonal antibodies. Additional information may be required for diagnosis.[22, 23]
- Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with *in vitro* immunoassays. Patients routinely exposed to animals or to animal serum products can be prone to this interference, and anomalous values may be observed. Additional information may be required for diagnosis.[24]

EXPECTED VALUES

A normal range of 0.35 µIU/mL to 4.94 µIU/mL (99% confidence interval) was obtained by testing serum specimens from 549 individuals defined as normal by the AxSYM Ultrasensitive hTSH II and AxSYM Free T_4 assays. It is recommended that each laboratory establish its own normal range which may be unique to the population it serves depending upon geographical, patient, dietary, or environmental factors.

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

The ARCHITECT TSH assay is designed to have a precision of ≤ 10% (total CV). A study based on guidance from Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) document EP5-A[25] was performed for the ARCHITECT TSH assay. Three buffer based panel members (1, 2 and 3) and three processed human serum based panel members (4, 5 and 6) were assayed, using two lots of reagents, in replicates of two at two separate times per day for 20 testing days. Data from this study are summarized in the following table.*

Panel Member	Reagent Lot	Instrument	n	Mean Conc. (µIU/mL)	Within Run SD	Within Run %CV	Total SD	Total %CV
1	1	1	80	0.0907	0.00160	1.8	0.00210	2.3
1	1	2	80	0.0879	0.00121	1.4	0.00171	1.9
1	2	1	80	0.0876	0.00135	1.5	0.00225	2.6
1	2	2	80	0.0888	0.00440	5.0	0.00469	5.3
2	1	1	80	5.7062	0.08187	1.4	0.12184	2.1
2	1	2	80	5.4750	0.09116	1.7	0.12761	2.3
2	2	1	80	5.5153	0.08122	1.5	0.11008	2.0
2	2	2	80	5.5320	0.08176	1.5	0.12501	2.3
3	1	1	80	28.4368	0.44471	1.6	0.82863	2.9
3	1	2	80	27.0156	0.76916	2.8	1.03741	3.8
3	2	1	80	27.2486	0.58176	2.1	0.75194	2.8
3	2	2	80	28.0434	0.55278	2.0	0.92480	3.3
4	1	1	80	0.5217	0.00655	1.3	0.00894	1.7
4	1	2	80	0.5024	0.00751	1.5	0.01128	2.2
4	2	1	80	0.4998	0.00653	1.3	0.00973	1.9
4	2	2	80	0.5070	0.00562	1.1	0.01156	2.3
5	1	1	80	2.0057	0.02380	1.2	0.03367	1.7
5	1	2	80	1.9318	0.02679	1.4	0.03842	2.0
5	2	1	80	1.9060	0.03844	2.0	0.04405	2.3
5	2	2	80	1.9369	0.02747	1.4	0.03499	1.8
6	1	1	80	16.5485	0.28656	1.7	0.38175	2.3
6	1	2	80	15.8935	0.27310	1.7	0.41347	2.6
6	2	1	80	15.9947	0.25055	1.6	0.38375	2.4
6	2	2	80	16.3632	0.23302	1.4	0.41631	2.5

* Representative data; results in individual laboratories may vary from these data.

Recovery

The ARCHITECT TSH assay is designed to have a mean recovery of 100 +/- 10% when analyzing samples spiked with known amounts of TSH. TSH (spanning the dynamic range) was added to 10 aliquots of human serum. The concentration of TSH was determined using the ARCHITECT TSH assay and the resulting percent recovery was calculated.* The percent recovery of the ARCHITECT TSH assay ranged from 91.8% to 104.3% with an average of 99.4%.

* Representative data; results in individual laboratories may vary from these data.

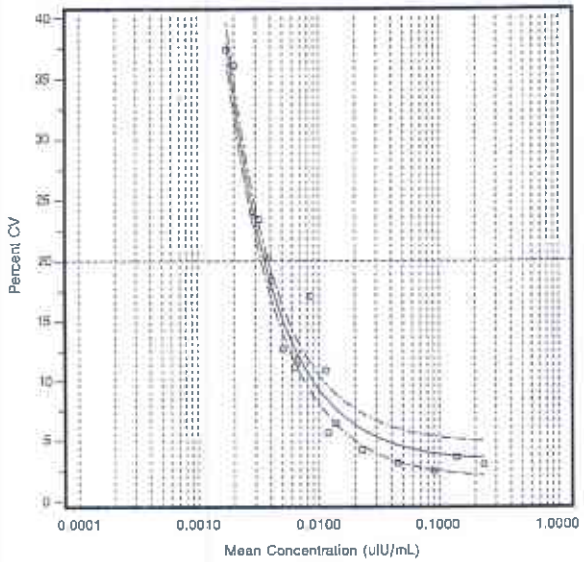
Sensitivity

Functional

Functional sensitivity is defined as the concentration of TSH that can be measured with an interassay CV of 20%.[6] The ARCHITECT TSH assay is designed to have a functional sensitivity of ≤ 0.01 µIU/mL, which meets the requirements of a third generation TSH assay.

In a representative study, the functional sensitivity was calculated to be ≤ 0.0038 µIU/mL (upper 95% confidence limit of 0.0042 µIU/mL). In addition, a total %CV was calculated from the pooled data generated using two lots of reagents and two instruments. The data exhibited a functional sensitivity of ≤ 0.0036 µIU/mL (upper 95% confidence limit of 0.0038 µIU/mL). This was determined by testing human serum and processed human serum samples ranging from 0.0007 µIU/mL to 0.2365 µIU/mL. Each sample was tested over 35 to 42 days on each of two ARCHITECT iSystems using two reagent lots with at least 10 replicates per lot per instrument. The total and interassay %CVs were calculated and plotted against the mean concentration. A reciprocal curve was fitted through the data and the functional sensitivity was estimated as the concentration corresponding to the 20% CV on the fitted curve.

ARCHITECT TSH
Functional Sensitivity by Precision Method
Both Instruments and Both Lots



---- 20%CV — Fitted Curve ---- 95% Confidence Limits of Fitted Curve
Model for the Curve: Reciprocal - X Y = a + b/X
Functional sensitivity: 0.0036, and 95% CI: (0.0034, 0.0038)

Analytical

The ARCHITECT TSH assay is designed to have an analytical sensitivity of ≤ 0.0025 µIU/mL.

Analytical sensitivity is defined as the concentration calculated as the mean plus two standard deviations of replicates of the ARCHITECT TSH MasterCheck Level 0 (0.0 µIU/mL). The analytical sensitivity (low-linearity) is defined in the ARCHITECT TSH assay parameters as 0.0025 µIU/mL.

Analytical Specificity

The ARCHITECT TSH assay is designed to have an analytical specificity of < 10% cross reactivity with the following substances, at the concentration levels listed, in human serum samples containing TSH in the normal range.

FSH	≤ 500 mIU/mL
LH	≤ 500 mIU/mL
hCG	≤ 200,000 mIU/mL

Interference

The ARCHITECT TSH assay is designed to have a potential interference from hemoglobin, bilirubin, triglycerides and protein of ≤ 10% at the levels indicated below.

Hemoglobin	≤ 500 mg/dL
Bilirubin	≤ 20 mg/dL
Triglycerides	≤ 3000 mg/dL
Protein	≤ 2 g/dL and 12 g/dL

Accuracy by Correlation

The ARCHITECT TSH assay is designed to have a slope of 1.0 +/- 0.2 and a correlation coefficient (r) of ≥ 0.95 when compared to the AxSYM Ultrasensitive hTSH II assay.

A study was performed where specimens were tested using the ARCHITECT TSH assay and AxSYM Ultrasensitive hTSH II assay. Data from this study were analyzed using least squares and Passing-Bablok[26] regression methods and are summarized in the following table.*

Abbott ARCHITECT TSH vs. Abbott AxSYM Ultrasensitive hTSH II

Method	Number of Specimens	Intercept	Slope	Correlation Coefficient
Least Squares Linear Regression	534	-0.7135	0.96	0.987
Passing-Bablok Linear Regression**	534	0.0098	0.91	0.987

In this evaluation, serum specimens tested ranged from 0.0109 µIU/mL to 127.9816 µIU/mL with the ARCHITECT TSH assay.

* Representative data; variables such as differences in sampling size and sample population may impact the correlation of the assay; therefore, results in individual laboratories may vary from these data.

** A linear regression method with no special assumptions regarding the distribution of the samples and the measurement errors.[26]

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Key to Symbols

	Consult Instructions for use
	Manufacturer
	Sufficient for
	Temperature limitation
	Use by/Expiration date
ASSAY DILUENT	Assay Diluent
CONJUGATE	Conjugate
CONTROL NO.	Control Number
INFORMATION FOR USA ONLY	Information needed for United States of America only
IVD	*In Vitro* Diagnostic Medical Device
LOT	Lot Number
MICROPARTICLES	Microparticles
MULTI-ASSAY MANUAL DILUENT	Multi-Assay Manual Diluent
PRE-TRIGGER SOLUTION	Pre-Trigger Solution
PRODUCT OF IRELAND	Product of Ireland
REACTION VESSELS	Reaction Vessels
REAGENT LOT	Reagent Lot
REF	List Number
REPLACEMENT CAPS	Replacement Caps
SAMPLE CUPS	Sample Cups
SEPTUM	Septum
SN	Serial number
TRIGGER SOLUTION	Trigger Solution
WARNING: SEVERE IRRITANT	Warning: Severe Irritant
WASH BUFFER	Wash Buffer

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