VIDAS® TSH (TSH)

IVD

The VIDAS® TSH (TSH) assay is intended for use on the instruments of the VIDAS family (Vitek® ImmunoDiagnostic Assay System) as an automated quantitative enzyme-linked fluorescent immunoassay (ELFA) for the determination of human thyroid stimulating hormone- (TSH) concentration in human serum or plasma (heparin). It is intended for use as an aid in the diagnosis of thyroid or pituitary disorders.

SUMMARY AND EXPLANATION OF THE TEST

Thyroid stimulating hormone (TSH), or thyrotropin, is a glycoprotein with a molecular weight of approximately 28,000 daltons. TSH is composed of alpha and beta subunits. The alpha subunit is very similar to that of FSH, LH, and hCG. The beta subunit determines the specific biological and immunological properties of the hormone.

TSH is secreted by the anterior pituitary gland in response to stimulation by thyrotropin releasing hormone (TRH), which is produced by the hypothalamus.

TSH stimulates the thyroid gland to produce thyroxine (T4) and 3,5,3'-triiodothyronine (T3). In turn, T3 and T4 regulate TSH release through a negative-feedback mechanism.

In cases of hyperthyroidism (Basedow's disease), thyroid adenoma, and inflammatory thyroiditis, the TSH production rate is severely decreased or even undetectable. In cases of primary hypothyroidism (congenital or acquired), TSH levels are high and the thyroid hormone levels are low due to the lack of response by the malfunctioning thyroid. TSH concentrations have also been used to differentiate secondary hypothyroidism (insufficient production of TSH by the pituitary) from tertiary hypothyroidism (hypothalmic disorder) by monitoring TSH in serial blood samples after a TRH stimulation test.

PRINCIPLE OF THE PROCEDURE

The VIDAS TSH (TSH) assay is an enzyme-linked fluorescent immunoassay (ELFA) that is performed in an automated instrument. All assay steps and assay temperature are controlled by the instrument. A pipette tip-like disposable device, the Solid Phase Receptacle (SPR®), serves as a solid phase for the assay as well as a pipetting device. The SPR is coated at the time of manufacture with mouse monoclonal anti-TSH antibodies. The VIDAS TSH (TSH) assay configuration prevents nonspecific reactions with the SPR. Reagents for the assay are located in the sealed Reagent Strips. The sample is transferred into the well containing anti-TSH antibody conjugated with alkaline phosphatase. The sample/conjugate mixture is cycled in and out of the SPR and the TSH will bind to antibodies coated on the SPR and to the conjugate forming a "sandwich".

Wash steps remove unbound conjugate. A fluorescent substrate, 4-methylumbelliferyl phosphate, is cycled through the SPR. Enzyme remaining on the SPR wall will catalyze the conversion of the substrate to the fluorescent product 4-methylumbelliferone. The intensity of fluorescence is measured by the optical scanner in the instrument ; it is proportional to the TSH concentration present in the sample.

When the VIDAS TSH (TSH) assay is completed, the results are analyzed automatically by the instrument, and a report is printed for each sample.

KIT COMPOSITION (60 TESTS):

60 TSH Reagent Strips	STR	Ready-to-use.
60 TSH SPRs (2 x 30)	SPR	Ready-to-use. SPRs are coated with mouse monoclonal anti-TSH antibodies.
TSH Control (lyophilized) (1 x 3 ml)	C1	Reconstitute with 3 ml of distilled water. Wait 5 to 10 minutes. Mix. Stable after reconstitution for 14 days at 2-8°C or until kit expiration date at -25 ± 6°C. Five freeze/thaw cycles are possible. Human sera* with human TSH and preservatives. MLE data indicate the confidence interval in µIU/mL ("Control C1 Dose Value Range").
TSH Calibrator (lyophilized) (1 x 2 ml)	S1	Reconstitute with 2 ml of distilled water. Wait 5 to 10 minutes. Mix. Stable after reconstitution for 14 days at 2-8°C or until kit expiration date at -25 ± 6°C. Five freeze/thaw cycles are possible. Calf sera with human TSH and preservatives. MLE data indicate the concentration in µIU/mL ("Calibrator (S1) Dose Value") and the confidence interval in "Relative Fluorescence Value ("Calibrator (S1) RFV Range").
TSH diluent (liquid) (1 x 3 ml)	R1	Ready-to-use. Calf sera with 1g/L sodium azide
Specifications for the factory master data required to calibrate the test: • MLE data (Master Lot Entry) provided in the kit, or • MLE bar codes printed on the box label		
1 Package Insert provided in the kit or downloadable from www.biomerieux.com/techlib.		

* This product has been tested and shown to be negative for HBs antigen, antibodies to HIV1, HIV2 and HCV. However, since no existing test method can totally guarantee their absence, this product must be treated as potentially infectious. Therefore, usual safety procedures should be observed when handling.

The SPR®

The interior of the SPR is coated during production with anti-TSH immunoglobulins (mouse). Each SPR is identified by the "TSH" code. Only remove the required number of SPRs from the pouch and **carefully reseal the pouch after opening**.

The strip

The strip consists of 10 wells covered with a labeled, foil seal. The label comprises a bar code which mainly indicates the assay code, kit lot number and expiration date. The foil of the first well is perforated to facilitate the introduction of the sample. The last well of each strip is a cuvette in which the fluorometric reading is performed. The wells in the center section of the strip contain the various reagents required for the assay.

Description of the TSH Reagent Strip:

Wells	Reagents
1	Sample well
2-3-4-5	Empty wells
6	Conjugate: Mouse monoclonal anti-TSH antibodies conjugated to alkaline phosphatase with 1 g/L sodium azide (400 µl).
7-8	Wash buffer: Sodium phosphate (0.01 mol/l, pH 7.4) with chemical stabilizers and 1 g/L sodium azide (600 µl)
9	Wash buffer: diethanolamine* (DEA) (1.1 mol/l or 11.5%, pH 9.8) with 1g/L sodium azide (600 µl)
10	Reading cuvette with substrate: 4-Methyl-umbelliferyl phosphate (0.6 mmol/l) + diethanolamine** (DEA) (0.62 mol/l or 6.6 %, pH 9.2) + 1 g/l sodium azide (300 µl).

* Signal Word: **DANGER**

Hazard statement

H318 : Causes serious eye damage.
H373 : May cause damage to organs through prolonged or repeated exposure.
H315 : Causes skin irritation.
H302 : Harmful if swallowed.

Precautionary statement

P280 :Wear protective gloves/protective clothing/eye protection/face protection.
P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P309 + P311 : IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.

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For further information, refer to the Safety Data Sheet.

MATERIAL REQUIRED BUT NOT PROVIDED

- Pipettor with disposable tips that will dispense 3 ml, 2 ml and 200 µl.
- Powderless disposable gloves.
- For other specific materials, please refer to the Instrument Operator's Manual.
- Instrument of the VIDAS family.

WARNINGS AND PRECAUTIONS

- **For *in vitro* diagnostic use only**.
- **For professional use only.**
- **This kit contains products of human origin. No known analysis method can totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled observing the usual safety precautions (see Laboratory biosafety manual - WHO - Geneva - latest edition).**
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not totally guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled observing the usual safety precautions (do not ingest or inhale).
- Consider all patient specimens potentially infectious and observe routine biosafety precautions. Dispose of all used components and other contaminated materials by acceptable procedures for potentially biohazardous human blood products.
- Do not mix reagents or disposables from different lots.
- Kit reagents contain 1g/L sodium azide which could react with lead or copper plumbing to form explosive metal azides. If any liquid containing sodium azide is disposed of in the plumbing system, drains should be flushed with water to avoid build-up.
- Powderless gloves are recommended as powder has been reported as a cause of false results in some enzyme immunoassays.
- The wash buffer (well 9) contains a harmful agent (11.5 % diethanolamine). Refer to the hazard statements "H" and the precautionary statements "P" above.
- The reading cuvette with substrate (well 10) contains an irritant agent (6.6% diethanolamine). Refer to the hazard statements "H" and the precautionary statements "P" above.
- Spills should be wiped up thoroughly after treatment with liquid detergent and a solution of household bleach containing at least 0.5% sodium hypochlorite to inactivate infectious agents. See the Operator's Manual for cleaning spills on or in the instrument. Do not place solutions containing bleach in the autoclave.
- The instrument should be routinely cleaned and decontaminated. See the Operator's Manual for the appropriate procedures.

STORAGE AND HANDLING

- Store the VIDAS TSH (TSH) kit at 2-8°C.
- **Do not freeze reagents, with the exception of calibrators and controls after reconstitution.**
- **Store all unused reagents at 2-8°C.**
- After opening the kit, check that the SPR pouch is correctly sealed and undamaged. If not, do not use the SPRs.
- **Carefully reseal the pouch with the desiccant inside after use to maintain stability of the SPRs and return the complete kit to 2-8°C.**
- If stored according to the recommended conditions, all components are stable until the expiration date indicated on the label. Refer to the kit composition table for special storage conditions.

SPECIMEN COLLECTION AND PREPARATION

Acceptable specimens include serum or plasma (with heparin anticoagulant). Do not use serum collected with EDTA. The use of heat-inactivated sera has not been established for this test - do not heat sera. Samples can be stored at 2-8°C in stoppered tubes for up to 2 days. If longer storage is required, freeze the sera or plasma at -25 ± 6°C. Avoid repeated cycles of freezing and thawing. If necessary, clarify samples by centrifugation.

INSTRUCTION FOR USE

For complete instructions, see the User's Manual.

Reading Master lot data

Before each new lot of reagents is used, enter the specifications (or factory master data) into the instrument using the master lot entry (MLE) data.
If this operation is not performed **before initiating the tests**, the instrument will not be able to print results.
Note: the master lot data need only be entered once for each lot. instructions for use

It is possible to enter MLE data **manually or automatically** depending on the instrument (refer to the User's Manual).

Calibration

Calibration, using the calibrator provided in the kit, must be performed upon receipt of a new lot of reagents after the master lot data have been entered. Calibration should then be performed every 14 days. This operation provides instrument-specific calibration curves and compensates for possible minor variations in assay signal throughout the shelf-life of the kit.
The calibrator, identified by S1, must be tested **in duplicate** (see Operator's Manual). The calibrator value must be within the set RFV "Relative Fluorescence Value" range. If this is not the case, recalibrate.

Assay Procedure

1. Remove necessary components from the kit and return all unused components to storage at 2-8°C.
2. Allow components to reach room temperature (approximately 30 minutes).
3. Use one "TSH" strip and one "TSH" SPR for each sample, control or calibrator to be tested. **Make sure the storage pouch has been carefully resealed after the required SPRs have been removed.**
4. The test is identified by the "TSH" code on the instrument. The calibrator must be identified by "S1" and tested **in duplicate**. If the control needs to be tested, it should be identified by C1.
5. If needed, label the "TSH" Reagent Strips with the appropriate sample identification numbers.
6. Mix the calibrator, control and samples using a vortex-type mixer (for serum or plasma separated from the pellet).
7. **For this test, the calibrator, control, and sample test portion is 200 µl.**
8. Insert the "TSH" Reagent Strips and SPRs into the appropriate position on the instrument. Check to make sure the color labels with the assay code on the SPRs and the Reagent Strips match.

9. Initiate the assay processing as directed in the Operator's Manual. All the assay steps are performed automatically by the instrument.
10. Reclose the vials and return them to the required temperature after pipetting.
11. The assay will be completed within approximately 40 minutes. After the assay is completed, remove the SPRs and strips from the instrument.
12. Dispose of the used SPRs and strips into an appropriate recipient.

QUALITY CONTROL

A control is included in each VIDAS TSH (TSH) kit. This control must be performed immediately after opening a new kit to ensure that the reagent performance has not been altered. Each calibration must also be checked using this control.
The instrument will only be able to check the control value if it is identified by C1.
Results cannot be validated if the control value deviates from the expected values.

Note

It is the responsibility of the user to perform Quality Control in accordance with any local applicable regulations.

RESULTS AND INTERPRETATION

Two instrument readings for fluorescence in the Reagent Strip's reading cuvette are taken for each specimen tested. The first reading is a background reading of the cuvette and substrate before the SPR® is introduced into the substrate. The second reading is taken after the substrate has been exposed to the enzyme conjugate remaining on the interior of the SPR. The background reading is subtracted from the final reading to give a Relative Fluorescence Value (RFV) for the test result. Samples with results greater than 60 µIU/ml must be diluted 1/2 (1 volume of sample and 1 volume of TSH diluent) or 1/4 (1 volume of sample and 3 volumes of TSH diluent). If the dilution factor has not been entered when the analysis has been requested (see Operator's Manual), multiply the result by the dilution factor to obtain the TSH sample concentration.

A report is printed which records :
- the type of test performed,
- the sample identification,
- the date and time,
- the lot number and the expiration date of the reagent kit being used,
- each sample's RFV and TSH concentration.

PERFORMANCE DATA

Immunological Specificity

The cross-reactivity percentage is the ratio between the compound concentration to be tested and the TSH concentration to be tested for a signal of 500 RFV. No cross-reactivity in the VIDAS® TSH (TSH) assay was observed with the compounds tested.

Tested compound	Cross-reactivity percentage
TSH (SCRIPPS Ref. T0115-lot n°148911)	100.0
FSH (SCRIPPS Ref. F0612-lot n°727991)	0.10
LH (SCRIPPS Ref. L0815-lot n°399711)	0.10
hCG free alpha subunit (SCRIPPS Ref. C0814-lot n°255091)	0.01
hCG (SCRIPPS Ref. C0714-lot n°210164)	0.01

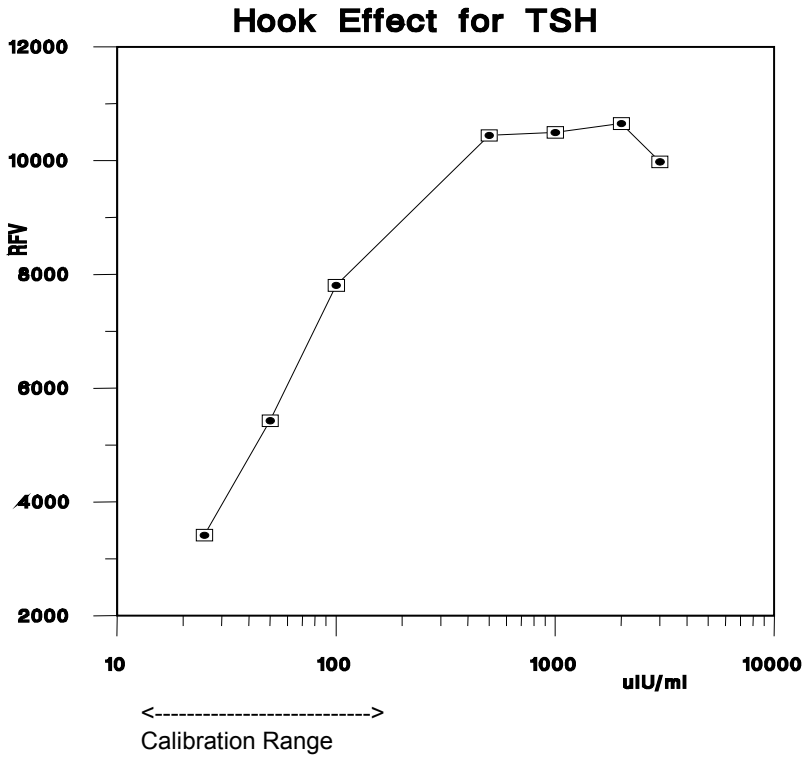
Immunological interference was tested by adding 250,000 mIU/ml of hCG, 10,000 mIU/ml of LH, or 10,000 mIU/ml of FSH to a sample containing 22.5 µIU/ml of TSH. No interference was seen with any of the compounds tested.

Detection limit

The detection limit (assay sensitivity) is defined as the lowest concentration that can be distinguished from zero with 95 % probability. The detection limit for the VIDAS TSH (TSH) assay is 0.05 µIU/ml.

Hook Effect

The Hook effect was performed on two different kit lots using TSH solutions whose respective concentrations were 25 to 3000 µIU/ml. No hook effect was seen up to 2000 µIU/ml.



PRECISION/REPRODUCIBILITY

Intra-assay reproducibility :

Five samples were tested for intra-assay precision. Thirty replicates of each sample were tested in the same run.

Sample	1	2	3	4	5
Mean concentration (µIU/ml)	1.50	1.88	8.28	24.90	33.40
% CV	4.7	4.1	2.8	3.7	2.4

Inter-assay reproducibility on the same instrument:

Five samples were tested in singlet on the same instrument over a 9-week period (recalibration was performed every 14 days as described in the Operator's Manual).

Sample	1	2	3	4	5
Mean concentration (µIU/ml)	0.84	2.21	8.05	20.50	31.40
% CV	3.5	4.3	3.1	3.8	3.2

Inter-instrument and inter-assay reproducibility:

Five samples were tested in singlet in 8 runs on different instruments.

Sample	1	2	3	4	5
Mean concentration (µIU/ml)	1.04	2.60	9.27	23.58	36.50
% CV	5.2	3.9	4.6	3.4	5.0

PARALLELISM (DILUTION TESTS)

Three samples were diluted in TSH diluent and tested in singlet in 3 runs.

Sample	Dilution factor	Expected mean concentration (µIU/ml)	Measured mean concentration (µIU/ml)	Mean recovery percentage
1	1/1	9.0	9.00	100.0
	1/2	4.5	4.36	97.3
	1/4	2.2	2.28	101.8
	1/8	1.1	1.12	100.1
	1/16	0.6	0.59	105.4
	1/32	0.3	0.27	96.2
2	1/1	22.5	22.5	100.0
	1/2	11.2	11.96	106.5
	1/4	5.6	5.91	105.2
	1/8	2.8	2.94	104.8
	1/16	1.4	1.51	107.8
	1/32	0.7	0.71	101.8
3	1/1	38.9	38.9	100.0
	1/2	19.5	17.9	92.0
	1/4	9.7	9.5	97.7
	1/8	4.9	4.64	95.4
	1/16	2.4	2.34	96.2
	1/32	1.2	1.1	90.5

Recovery tests

Three samples were spiked with known quantities of TSH (µIU/ml, 2nd IRP 80/558) and tested in singlet in 3 instrument runs. The measured mean concentration compared to the expected mean concentration is shown below.

Sample	Amount spiked (µIU/ml)	Expected mean concentration (µIU/ml)	Measured mean concentration (µIU/ml)	Mean recovery percentage
1	0	2.70	2.70	100.0
	0.80	3.50	3.56	101.4
	4.37	7.10	7.27	102.6
	10.30	13.00	12.52	96.2
	24.10	26.80	26.17	97.6
	44.00	46.70	45.84	98.1
2	0	9.50	9.48	100.0
	0.80	10.30	11.36	110.4
	4.37	13.90	15.16	109.4
	10.30	19.80	20.35	102.9
	24.10	33.60	32.93	98.0
	44.00	53.50	54.02	101.0
3	0	24.70	24.67	100.0
	0.80	25.50	27.27	107.1
	4.37	29.00	29.65	102.1
	10.30	35.00	35.49	101.5
	24.10	48.80	49.63	101.8
	44.00	68.70	> 60.00	--------

INFLUENCE OF SPECIMEN COLLECTION

Blood samples were collected from thirty patients. For each patient, 5 specimens were collected at the same time: in a tube with beads, in a dry glass tube in a tube with separating gel; in a heparinized tube; and in an EDTA tube. Each sample collected was tested in duplicate and sera from the same donor were tested in the same run. The tube with beads was the reference to which the other methods were compared.

Collection tube	Equation of the line	Correlation coefficient
Dry glass tube	0.96 Ref. + 0.04	0.99
Tube with separating gel	0.97 Ref. + 0.01	0.99
Tube with heparin (lithium)	0.93 Ref. + 0.05	0.99
Tube with EDTA	0.67 Ref. - 0.02	0.89

A decrease in values is observed with EDTA tubes. Do not use EDTA plasma with the VIDAS® TSH (TSH) assay.

INTERFERENCE STUDIES

Heparin

Three pools of human sera were spiked with increasing quantities of heparin.

		Amount of heparin spiked (U/ml)			
		0	0.5	5	50
TSH (µIU/ml)	Pool 1	0.9	0.9	0.9	0.9
	Pool 2	8.7	8.7	8.7	8.6
	Pool 3	40.3	37.0	36.6	36.0

EDTA

Three pools of human samples were spiked with increasing quantities of EDTA.

		Amount of EDTA spiked (mg/ml)			
		0	1	5	10
TSH (µIU/ml)	Pool 1	0.90	0.90	0.30	0.10
	Pool 2	8.70	8.40	3.80	1.70
	Pool 3	40.30	38.50	14.30	5.00

The presence of EDTA in the samples leads to a decrease in values. Only plasma collected with heparin can be used.

Hemoglobin

Three pools of human sera were spiked with increasing quantities of hemoglobin obtained from a lysate of human red blood cells.

		Amount of hemoglobin spiked (µmol/l)						
		0	15	30	60	150	210	300
TSH (µIU/ml)	Pool 1	1.01	1.00	1.03	1.02	1.08	1.06	1.00
	Pool 2	9.34	9.90	10.00	9.56	9.52	10.06	9.44
	Pool 3	37.14	38.01	38.03	38.38	36.74	37.80	40.35

Lipids

Three pools of human sera were spiked with increasing quantities of a lipid solution.

		Amount of triglycerides spiked (mmol/l)				
		0	1.0	2.6	3.0	5.0
TSH (µIU/ml)	Pool 1	1.00	0.98	1.03	1.05	1.01
	Pool 2	9.42	9.05	9.39	9.25	9.62
	Pool 3	36.56	41.70	37.58	37.43	38.22
Appearance		Clear	Opalescent		Turbid	

Bilirubin

Three pools of human sera were spiked with increasing quantities of bilirubin.

		Amount of bilirubin spiked (µmol/l)						
		0	25.6	51.3	102.6	256	385	513
TSH (µIU/ml)	Pool 1	0.97	1.01	1.01	1.00	1.06	1.09	0.97
	Pool 2	9.23	9.73	9.47	10.03	9.68	9.07	9.80
	Pool 3	36.58	37.70	37.24	37.77	37.80	37.24	37.03

Although interference linked to the presence of hemoglobin, bilirubin or to turbidity has not been observed, using hemolyzed, icteric or lipemic samples is not recommended. If possible, collect a new specimen.

EXPECTED VALUES

In a study performed at bioMerieux (Marcy l'Etoile, France), approximately 60 samples were tested, including specimens from euthyroid, hyperthyroid, and hypothyroid patients. This study confirmed the expected values listed below. The results are expressed in µIU/ml (2nd IRP 80/558)

Sample	Result
- Euthyroid :	0.25 - 5 µIU/ml
- Hyperthyroid :	< 0.15 µIU/ml
- Hypothyroid :	> 7 µIU/ml

CORRELATION

One hundred ninety-seven specimens were tested at a clinical chemistry laboratory. Samples were tested using the VIDAS® TSH (TSH) assay and a commercially available TSH EIA. A summary of the results is shown below.

# of Samples	Slope	Intercept	Correlation Coefficient
197	1.42	-0.26	0.988

WASTE DISPOSAL

Dispose of used or unused reagents as well as any other contaminated disposable materials following procedures for infectious or potentially infectious products.
It is the responsibility of each laboratory to handle waste and effluents produced according to their nature and degree of hazardousness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

LITERATURE REFERENCES

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INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalog number
IVD	*In Vitro* Diagnostic Medical Device
	Manufacturer
	Temperature limit
	Use by date
LOT	Batch code
	Consult Instructions for Use
	Contains sufficient for <n> tests
	Date of manufacture

WARRANTY

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REVISION HISTORY

Change type categories :

N/A	Not applicable (First publication)
Correction	Correction of documentation anomalies
Technical change	Addition, revision and/or removal of information related to the product
Administrative	Implementation of non-technical changes noticeable to the user
	Minor typographical, grammar, and formatting changes are not included in the revision history.

Release date	Part Number	Change Type	Change Summary
2015/01	13671E	Administrative	INDEX OF SYMBOLS REVISION HISTORY
		Technical	KIT COMPOSITION (60 tests) WARNINGS AND PRECAUTIONS
2015/10	13671F	Technical	KIT COMPOSITION (60 tests) INSTRUCTION FOR USE

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