510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k141133

B. Purpose for Submission:

Clearance of VIDAS 3 analyzer and 9 previously cleared VIDAS representative assays. (The 9 previously cleared VIDAS representative assays are being used to assess the VIDAS 3 performance with multiple analytes across the dynamic range of the new instrument. The assays have not changed since their original clearance.)

C. Measurand:

H. pylori IgG, Lyme IgG, Rubella IgG, TOXO IgM, Human Chorionic Gonadotropin (HCG), Thyroxine (T4), Testosterone (TES), Thyroid Stimulating Hormone (TSH) and D-Dimer.

D. Type of Test:

Immunoassay, Enzyme Linked Fluorescent Assay

E. Applicant:

bioMerieux, Inc.

F. Proprietary and Established Names:

VIDAS 3, VIDAS *H. pylori* IgG, VIDAS Lyme IgG II, VIDAS RUB IgG, VIDAS TOXO M, VIDAS Human Chorionic Gonadotropin, VIDAS T4, VIDAS Testosterone, VIDAS TSH, and VIDAS D-Dimer Exclusion II.

G. Regulatory Information:

1. Regulation section:
   VIDAS 3 - 21 CFR 862.2160 Analyzer, chemistry (photometric, discrete), for clinical use
   VIDAS *H. pylori* IgG -21 CFR 866.3110 *Campylobacter fetus* serological reagents
   VIDAS Lyme IgG II - 21 CFR 866.3830 Treponema pallidum treponemal test reagents
   VIDAS RUB IgG - 21 CFR 866.3510 Rubella virus serological reagents
   VIDAS TOXO M - 21 CFR 866.3780 Toxoplasma gondiiserological reagents
   VIDAS Human Chorionic Gonadotropin - 21 CFR 862.1155 Human chorionic gonadotropin (HCG) test system

VIDAS T4 - 21 CFR 862.1700 Total thyroxine test system
VIDAS Testosterone - 21 CFR 862.1680 Testosterone test system
VIDAS TSH - 21 CFR 862.1690 Thyroid stimulating hormone test system
VIDAS D-Dimer Exclusion II - 21 CFR 864.7320 Fibrinogen and fibrin split products, antigen, antiserum, control

2. Classification:
   VIDAS 3 - Class I
   VIDAS *H. pylori* IgG - Class I
   VIDAS Lyme IgG II - Class II
   VIDAS RUB IgG - Class II
   VIDAS TOXO M - Class II
   VIDAS Human Chorionic Gonadotropin - Class II
   VIDAS T4 - Class II
   VIDAS Testosterone - Class I, reserved
   VIDAS TSH - Class II
   VIDAS D-Dimer Exclusion II - Class II

3. Product code:
   VIDAS 3 - JJE
   VIDAS *H. pylori* IgG - LYR
   VIDAS Lyme IgG II - LSR
   VIDAS RUB IgG - LFX
   VIDAS TOXO M - LGD
   VIDAS Human Chorionic Gonadotropin - DHA
   VIDAS T4 - KLI
   VIDAS Testosterone - CDZ
   VIDAS TSH - JLW
   VIDAS D-Dimer Exclusion II - DAP

4. Panel:
   VIDAS 3 - Clinical Chemistry
   VIDAS *H. pylori* IgG - Microbiology
   VIDAS Lyme IgG II - Microbiology
   VIDAS RUB IgG - Microbiology
   VIDAS TOXO M - Microbiology
   VIDAS Human Chorionic Gonadotropin - Clinical Chemistry
   VIDAS T4 - Clinical Chemistry
   VIDAS Testosterone - Clinical Chemistry
   VIDAS TSH - Clinical Chemistry
   VIDAS D-Dimer Exclusion II - Hematology

H. Intended Use:

1. Intended use(s):

VIDAS 3

The VIDAS 3 system is a complete standalone immunodiagnostic system intended for trained and qualified laboratory technicians (daily routine use) and laboratory administrators (application configuration).

This device is an in vitro diagnostic medical device for professional use only.

VIDAS *H. pylori* IgG

VIDAS *H. pylori* IgG (HPY) is an automated qualitative test for use on the instruments of the VIDAS family, for the detection of anti-*Helicobacter pylori* IgG antibodies in human serum or plasma (EDTA) using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS HPY assay is intended as an aid in diagnosis of *H. pylori* infection in an adult symptomatic population.

This device is an in vitro diagnostic medical device for professional use only.

VIDAS Lyme IgG II

The VIDAS Lyme IgG II (LYG) assay is an automated qualitative enzyme immunoassay intended for use on the instruments of the VIDAS family in the presumptive detection of human IgG antibodies to *Borrelia burgdorferi* in human serum (plain or separation gel) or plasma (sodium heparin or lithium heparin). It should be used to test patients with a history and/or symptoms of infection with *B. burgdorferi*. All VIDAS Lyme IgG II positive specimens should be further tested with a Western Blot IgG assay to obtain supportive evidence of infection with *B. burgdorferi*.

This device is an in vitro diagnostic medical device for professional use only.

VIDAS RUB IgG

The VIDAS RUB IgG (RBG) assay uses Enzyme Linked Fluorescent Assay (ELFA) technology on the instruments of the VIDAS family for the *in vitro* quantitative and qualitative measurement of IgG antibodies to rubella virus in human serum. The VIDAS RUB IgG (RBG) assay is intended as an aid in the determination of immune status to rubella. The performance of this device has not been established for screening of cord blood, or for neonatal samples. Likewise, performance characteristics of the assay have not been established for immunocompromised or immunosuppressed individuals.

This device is an in vitro diagnostic medical device for professional use only.

VIDAS TOXO M

The VIDAS TOXO IgM (TXM) assay is intended for use on the instruments of the VIDAS family (VITEK ImmunoDiagnostic Assay System) as an automated enzyme-linked fluorescent immunoassay (ELFA) for the presumptive qualitative detection of anti-Toxoplasma gondii IgM antibodies in human serum, as an aid in the diagnosis of acute,

recent, or reactivated Toxoplasma gondii infection. This assay must be performed in conjunction with an anti-Toxoplasma gondii lgG antibody assay. VIDAS TOXO IgM (TXM) assay performance has not been established for prenatal screening or newborn testing. This assay has not been cleared by the FDA for blood/plasma donor screening.

This device is an in vitro diagnostic medical device for professional use only.

VIDAS Human Chorionic Gonadotropin

The VIDAS HCG (HCG) assay is intended for use on the instruments of the VIDAS family as an automated quantitative enzyme linked fluorescent immunoassay (ELFA) for the determination of human Chorionic Gonadotropin (hCG) concentration in human serum or plasma. The VIDAS HCG (HCG) assay is intended to aid in the early detection of pregnancy.

This device is an in vitro diagnostic medical device for professional use only.

VIDAS T4

The VIDAS T4 (T4) assay is intended for use on the instruments of the VIDAS family as an automated quantitative enzyme-linked fluorescent immunoassay for the determination of human thyroxine (T4) concentration in serum or plasma (heparin). It is intended for use as an aid in the diagnosis and treatment of thyroid disorders.

This device is an in vitro diagnostic medical device for professional use only.

VIDAS Testosterone

VIDAS Testosterone (TES) is an automated quantitative test for use on the instruments of the VIDAS family for the enzyme immunoassay measure of total testosterone in human serum or plasma (lithium heparin), using the ELFA technique (Enzyme Linked Fluorescent Assay). It is intended as an aid in the diagnosis and management of conditions involving excess or deficiency of this androgen.

This device is an in vitro diagnostic medical device for professional use only.

VIDAS TSH

The VIDAS TSH (TSH) assay is intended for use on the instruments of the VIDAS family 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.

This device is an in vitro diagnostic medical device for professional use only.

VIDAS D-Dimer Exclusion II

VIDAS D-Dimer Exclusion II is an automated quantitative test for use on the instruments of the VIDAS family for the immunoenzymatic determination of fibrin degradation products (FbDP) in human plasma (sodium citrate, CTAD) using the ELFA technique

(Enzyme Linked Fluorescent Assay). VIDAS D-Dimer Exclusion II is indicated for use in conjunction with a clinical pretest probability assessment model to exclude deep vein thrombosis (DVT) and pulmonary embolism (PE) disease in outpatients suspected of DVT or PE.

This device is an in vitro diagnostic medical device for professional use only.

2. Indication(s) for use:

   Same as intended use

3. Special conditions for use statement(s):

   Prescription use

4. Special instrument requirements:

   Performance studies were obtained from the VIDAS 3 analyzer

   This device is not for Point-of-Care use

I. Device Description:

VIDAS 3 - The VIDAS® 3 instrument is an automated multiparametric immunoassay system, which uses ELFA (Enzyme Linked Fluorescent Assay) technology. The VIDAS 3 system offers primary tube sampling, automated sample dilution, reagent/sample detection and reagent traceability.

VIDAS *H. pylori* IgG – See k001460 for device description.

VIDAS Lyme IgG II - See k122986 for device description.

VIDAS RUB IgG - See k080766 for device description.

VIDAS TOXO M - See k923166 for device description.

VIDAS Human Chorionic Gonadotropin - See k921302 for device description.

VIDAS T4 - See k926393 for device description.

VIDAS Testosterone - See k021326 for device description.

VIDAS TSH - See k921816 for device description.

VIDAS D-Dimer Exclusion II - See k112818 for device description.

J. Substantial Equivalence Information: (Note: This information is for the predicate instrument (VIDAS) and new instrument (VIDAS 3) only. The previously cleared representative VIDAS assays have not changed. They are the same whether they are run on the VIDAS or VIDAS 3 instruments.)

1. Predicate device name(s):
   VIDAS Instrument

2. Predicate 510(k) number(s):
   k891385

3. Comparison with predicate:

Similarities		
Item	Device (VIDAS 3)	Predicate (VIDAS)
Technology	Automated multiparametric immunoassay system which uses ELFA (Enzyme Linked Fluorescent Assay) technology.	Same
Computer	Peripheral	Same
Keyboard	Peripheral	Same
Printer	Peripheral	Same
Components (Scanner head)	The scanner head is an instrument sub-system that's primary function is to perform the optical reading of the fluorescence as generated by the immunoassay reaction.	Same
Components (Reagents)	VIDAS reagents are comprised of predispensed disposable reagent strips and specially coated Solid Phase Receptacles (SPRs).	Same
Reagent (Principle of Operation)	Each VIDAS assay has been designed to be run on any of the three VIDAS family instruments. Each assay has a unique protocol (volumes, sequence of steps, incubation times, etc) that is independent of the instrument.	Same
Reagent	The assay intended use,	Same

Similarities		
Item	Device (VIDAS 3)	Predicate (VIDAS)
	clinical utility, principle of operation, kit composition, kit stability, kit storage conditions, calibration type, calibration frequency, sample type, sample volume, calculation of results, and interpretation of results are all independent of the instrument.	
Reagent Loading	Manual	Same
Execution of the assay protocol	Each assay has its own pre-defined protocol that defines the sequence of assay steps (e.g. volumes, incubation times, order of steps).	Same
Enzymatic Reading	The reading made by the scanner head is based on the 4-methylumbelliferone (4-MU) fluorescent product located in the optical cuvette of the reagent strip after the enzymatic reaction has occurred.	Same
Calculation and Interpretation of results	Data reduction of the fluorescence measurement is based upon computation engine and a knowledge base including assay and lot specific information.	Same
Unload Strips / SPRs	After completion of the run, the user manually removes the reagent Strips and SPRs.	Same

Differences		
Item	Device (VIDAS 3)	Predicate (VIDAS)
Indication for Use	The VIDAS 3 system is a complete standalone immunodiagnostic system intended for trained and qualified laboratory technicians (daily routine use) and laboratory administrators (application	The VIDAS® is a compact automated multiparametric immunoanalyzer that using predispensed disposable reagent strips and specially coated Solid Phase Receptacles (SPRs), can pipette, mix, incubate,

Differences		
Item	Device (VIDAS 3)	Predicate (VIDAS)
	configuration). This device is an in vitro diagnostic medical device for professional use only.	control and analyze samples for in vitro diagnostic purposes. The VIDAS is only dedicated to be used in combination with VIDAS reagents range, designed and produced by bioMérieux. The technology used, which is adaptable to a wide range of assays, combines the EIA method with a final fluorescence reading: this technology is known as ELFA (Enzyme Linked Fluorescent Assay). The enzyme used in the VIDAS product range is alkaline phosphatase, which catalyzes the hydrolysis of the substrate 4-methyl umbelliferyl phosphate (4-MUP) into a fluorescent product 4-methyl umbelliferone (4-MU) the fluorescence of which is measured at 450nm. The immunological methods are either indirect EIA, immunocapture, sandwich or competition, all involving a conjugate using the alkaline phosphatase. This device is an in vitro diagnostic medical device for professional use only.
# Sections	4	5
Reagent slots per section	3	6
Total # samples that can be run	12	30

Differences		
Item	Device (VIDAS 3)	Predicate (VIDAS)
simultaneously		
Monitor	Peripheral (Attached)	Peripheral
Components (Software)	The user Software functions include: entry of patient data; run execution; data reduction and interpretation through a computation engine; edition of results; system supervision; management of calibrations and controls; validation of results; management of patient records.	While the VIDAS 3 software is unique to the VIDAS 3, it offers the same basic functions as the VIDAS software and uses the same computation engine.
SPR/Strip synchronization	Automated confirmation	Manual
Sample Pipetting	Manual or automated	Manual
Sample dilutions	Manual or automated	Manual

K. Standard/Guidance Document Referenced (if applicable):

- CLSI EP05-A2; Evaluation of Precision Performance of Quantitative Measurement Methods; August 2004
- CLSI EP06-A Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; April 2003
- CLSI EP09-A2-IR Method Comparison and Bias Estimation Using Patient Samples; January 2012
- CLSI EP12-A2 User Protocol for Evaluation of Qualitative Test Performance; January 2008
- CLSI EP15-A2 User Verification of Performance for Precision and Trueness; April 2006
- CLSI EP17-A2 Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; June 2012
- CLSI AUTO11-A IT Security of In Vitro Diagnostic Instruments and Software Systems; Approved Standard; October 2006
- IEC 61326:2005 Electrical equipment for measurement, control and laboratory use - EMC requirements; 2005

L. Test Principle:

VIDAS 3

The technology used, which is adaptable to a wide range of assays, combines the EIA method with a final fluorescence reading: this technology is known as ELFA (Enzyme Linked Fluorescent Assay). The enzyme used in the VIDAS product range is alkaline phosphatase, which catalyzes the hydrolysis of the substrate 4-methyl umbelliferyl phosphate

(4-MUP) into a fluorescent product 4-methylumbelliferone (4-MU) the fluorescence of which is measured at 450nm. The immunological methods are either indirect EIA, immunocapture, sandwich or competition, all involving a conjugate using the alkaline phosphatase.

VIDAS *H. pylori* IgG – See k001460 for test principle.

VIDAS Lyme IgG II - See k122986 for test principle.

VIDAS RUB IgG - See k080766 for test principle.

VIDAS TOXO M - See k923166 for test principle.

VIDAS Human Chorionic Gonadotropin - See k921302 for test principle.

VIDAS T4 - See k926393 for test principle.

VIDAS Testosterone - See k021326 for test principle.

VIDAS TSH - See k921816 for test principle.

VIDAS D-Dimer Exclusion II - See k112818 for test principle.

M. Performance Characteristics (if/when applicable):

I. VIDAS *H. pylori* IgG

1. Analytical performance: VIDAS *H. pylori* IgG

   a. Precision/Reproducibility:

   Precision
   Three serum samples with samples close to the assay cut-off and moderate positive samples were tested in triplicate (3 replicates) twice a day (2 runs per day) over 6 days on 1 reagent lot using 3 instruments at 1 site (N = 108). The repeatability (within-run precision), between-run, between-day, between calibration, between instrument, total between calibration, and total between instrument precision were calculated according to CLSI EP5-A2 *"Evaluation of Precision Performance of Quantitative Measurement Methods" and* CLSI EP12-A2 "*User Protocol for Evaluation of Qualitative Test Performance; Approved guideline – Second Edition"*.

   The results were as follows:

	Sample 1		Sample 2		Sample 3	
	N = 108		N = 108		N = 108	
	Mean Test Value (TV) 0.76		Mean Test Value (TV) 1.26		Mean Test Value (TV) 2.23	
	SD	CV (%)	SD	CV (%)	SD	CV (%)
Within-RUN (Repeatability)	0.06	7.7	0.08	6.2	0.12	5.2
Between-RUN	0.04	5.7	0.04	3.0	0.04	1.7
Between-DAY	0.00	0.0	0.00	0.0	0.05	2.4
Between-CALIBRATION	0.01	2.0	0.03	2.0	0.05	2.1
Between-INSTRUMENT	0.02	2.4	0.00	0.0	0.05	2.3
Total Between-CALIBRATION	0.07	9.8	0.09	7.2	0.14	6.4
Total Between-INSTRUMENT	0.08	10.1	0.09	7.2	0.15	6.8

b. Linearity/assay reportable range:

Not applicable.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Previously reviewed in k001460.

d. Detection limit:

Not applicable.

e. Analytical specificity:

Previously reviewed in k001460.

f. Assay cut-off:

Not applicable.

2. Comparison studies: VIDAS *H. pylori* IgG

a. Method comparison with predicate device:

Method Comparison - Qualitative

A study was conducted to verify the correlation of the VIDAS *H. pylori* IgG assay on the VIDAS 3 to the VIDAS *H. pylori* IgG assay on the VIDAS. One reagent lot, one of each instrument and 250 serum samples including positive, equivocal and negative samples were used, and results were evaluated according to CLSI EP12-A2 guideline "*User Protocol for Evaluation of Qualitative Test Performance; Approved guideline*".

Contingency Table:

		VIDAS			
		Positive	**Equivocal**	**Negative**	**Total**
VIDAS 3	**Positive**	122	3	0	125
	Equivocal	0	6	4	10
	Negative	0	2	113	115
	Total	122	11	117	250

Associated percent agreements and their 95% two-sided score confidence intervals (CI) are calculated below:

Category	**Samples of interest/Total**	**Percent Agreement 2-sided 95% CI**
Negative	113/117	96.6% [91.5 ; 98.7] %
Positive	122/122	100% [96.9 ; 100.0] %

b. Matrix comparison:

Previously reviewed in k001460.

3. Clinical studies: VIDAS *H. pylori* IgG

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off**:** VIDAS *H. pylori* IgG

Not applicable.

5. Expected values/Reference range: VIDAS *H. pylori* IgG

Previously reviewed in k001460.

II. VIDAS Lyme IgG II

1. Analytical performance: VIDAS Lyme IgG II

a. Precision/Reproducibility:

Precision
Three serum samples were tested in triplicate (3 replicates) twice a day (2 runs per day) over 6 days on 1 reagent lot using 3 instruments at 1 site (N = 108). The results were calculated according to CLSI EP5-A2 *"Evaluation of Precision Performance of Quantitative Measurement Methods"* and were as follows:

Panel Member	N	Mean Index	Within-run		Between-run		Between-day		Total Between Instrument	
			SD	CV (%)	SD	CV (%)	SD	CV (%)	SD	CV (%)
Sample 1	108	0.17	0.01	5.4	0.00	0.0	0.00	1.8	0.01	8.2
Sample 2	108	0.23	0.01	4.0	0.00	0.9	0.00	1.0	0.02	6.9
Sample 3	108	0.64	0.02	3.4	0.00	0.0	0.00	0.0	0.04	6.2

b. Linearity/assay reportable range:

Not Applicable.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Previously reviewed in k122986.

d. Detection limit:

Not Applicable.

e. Analytical specificity:

Previously reviewed in k122986.

f. Assay cut-off:

Not Applicable.

2. Comparison studies: VIDAS Lyme IgG II

a. Method comparison with predicate device:
A study was conducted to verify the correlation of the VIDAS Lyme IgG assay on the VIDAS 3 to the VIDAS Lyme IgG assay on the VIDAS. One reagent lot, one of each instrument and 220 serum samples including positive and negative samples were used. Results were evaluated according to CLSI EP12-A2 guideline"*User Protocol for Evaluation of Qualitative Test Performance; Approved guideline*".

Contingency Table:

		VIDAS		
		Positive	Negative	Total
VIDAS 3	Positive	109	0	109
	Negative	1	110	111
	Total	110	110	220

Associated percent agreements and their 95% two-sided score confidence intervals are presented in the table below:

Category	**Samples of Interest/Total**	**Percent Agreement 2-sided 95% CI**
Positive	109/110	99.09% [95.04;99.98] %
Negative	110/110	100.00% [96.70;100.00] %

b. Matrix comparison:

Previously reviewed in k122986.

3. Clinical studies: VIDAS Lyme IgG II

a. Clinical Sensitivity:

Not Applicable.

b. Clinical specificity:

Not Applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not Applicable.

4. Clinical cut-off: VIDAS Lyme IgG II

Not Applicable.

5. Expected values/Reference range: VIDAS Lyme IgG II

Previously reviewed in k122986.

III. VIDAS RUB IgG

1. Analytical performance: VIDAS RUB IgG

a. Precision/Reproducibility:

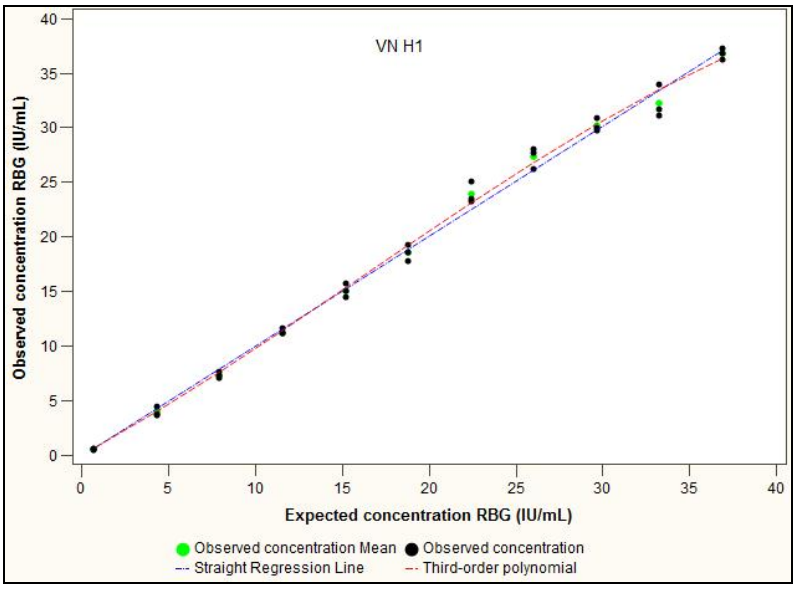
Precision
Five serum samples (with 2 samples close to the clinical decision points) were tested in duplicate (2 replicates) twice a day (2 runs per day) over 6 days on 1 reagent lot using 3 instruments at 1 site (N = 72). The repeatability (within-run precision), between-run, between-day, between calibration, between instrument, total between calibration, and total between instrument precision were calculated according to CLSI EP5-A2. *"Evaluation of Precision Performance of Quantitative Measurement Methods"*. The results were as follows:

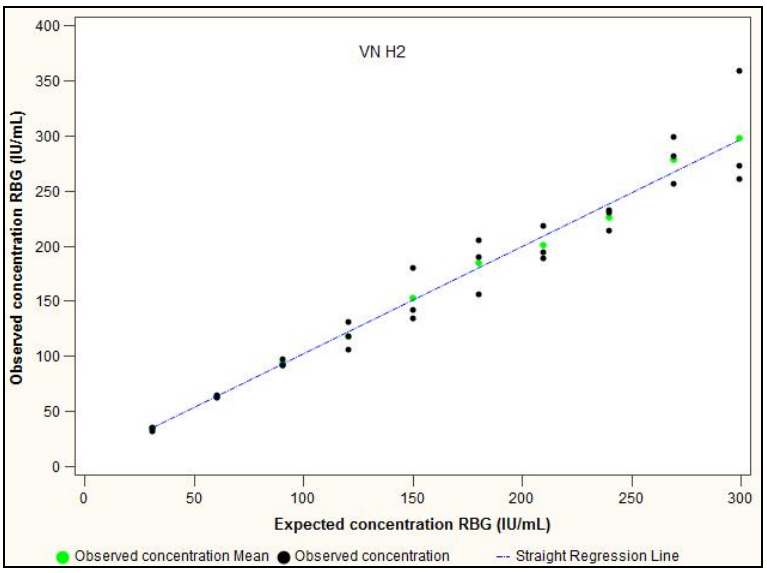
	Sample 1		**Sample 2**		**Sample 3**		**Sample 4**		**Sample 5**	
	N = 72		**N = 72**		**N = 72**		**N = 72**		**N = 72**	
	Mean (IU/mL) 2.69		**Mean (IU/mL) 5.81**		**Mean (IU/mL) 12.82**		**Mean (IU/mL) 28.93**		**Mean (IU/mL) 132.88**	
	SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Within-RUN (Repeatability)	0.41	15.2	0.55	9.5	0.74	5.7	2.39	8.3	10.24	7.7
Between-RUN	0.29	10.7	0.00	0.0	0.00	0.0	0.00	0.0	0.00	0.0
Between-DAY	0.00	0.0	0.00	0.0	0.19	1.5	0.43	1.5	0.00	0.0
Between-CALIBRATION	0.00	0.0	0.10	1.8	0.33	2.6	0.75	2.6	5.25	4.0
Between-INSTRUMENT	0.09	3.5	0.00	0.0	0.00	0.0	0.00	0.0	0.00	0.0
Total Between-CALIBRATION	0.50	18.6	0.56	9.7	0.83	6.5	2.54	8.8	11.51	8.7
Total Between-INSTRUMENT	0.51	18.9	0.56	9.7	0.83	6.5	2.54	8.8	11.51	8.7

b. Linearity/assay reportable range:

Linearity

Two sample pools (VNH1 and VNH2) were serially diluted into a total of 11 samples and tested in triplicate in order to evaluate the linearity according to CLSI EP06-A "*Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach*". The VIDAS RUB IgG assay on VIDAS 3 is linear across the measuring range 0 - 250 IU/mL





c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Previously reviewed in k080766.

d. *Detection limit:*

The detection limits of the VIDAS RUB IgG assay on the VIDAS 3 were evaluated per CLSI EP17-A2 "*Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline, Second Edition*". For LoB determination, 6 blank samples were each tested in 4 replicates in a single run per day for 4 days with 1 VIDAS 3 instrument and 2 assay lots. For LoD/LoQ determinations, 6 low-level samples were each tested in 6 replicates, 2 runs per day, for 5 days, with 1 VIDAS 3 instrument and 2 assay lots. The LoB, LoD and LoQ determinations were based consequently on 912 results, including 192 results from blank samples and 720 results from low-level samples both assay lots combined. The LoB, LoD, LoQ of the VIDAS RUB IgG assay on the VIDAS 3 are as follows: LoB = 0.389 IU/mL; LoD = 0.595 IU/mL; LoQ = 0.608 IU/mL.

e. *Analytical specificity:*

Previously reviewed in k080766.

f. *Assay cut-off:*

Not Applicable.

2. Comparison studies: VIDAS RUB IgG

a. *Method comparison with predicate device:*

Method Comparison – Quantitative
A study was conducted to verify the correlation of the VIDAS RUB IgG assay on the VIDAS 3 to the VIDAS RUB IgG assay on the VIDAS. One reagent lot, one of each instrument and 112 serum samples (ranging from 0 to 225 IU/mL) were used, and results were evaluated according to CLSI EP9. *"Method Comparison and Bias Estimation Using Patient Samples"*. The results were as follows:

Analysis	**N**	**Slope**	**Intercept**	**Correlation coefficient**
Weighted Deming	91*	0.9791	-0.2245	0.9776
Passing Bablock	112	1.00	0.00	0.9821
Weighted Deming	89**	0.9640	-0.2343	0.9805
Passing Bablock	111**	1.00	0.00	0.9840

* 21 samples had an average concentration equal to zero for VIDAS 3 and/or VIDAS, and were excluded from the Weighted Deming analysis.
** After removal of outliers.

Method Comparison – Qualitative
A study was conducted to verify the correlation of the VIDAS RUB IgG assay on the VIDAS 3 to the VIDAS RUB IgG assay on the VIDAS. One reagent lot, one of each instrument and 220 serum samples including positive, equivocal and negative samples were used, and results were evaluated according to CLSI EP12-A2 guideline "*User Protocol for Evaluation of Qualitative Test Performance; Approved guideline*".

Contingency Table:

		VIDAS			
		Positive	**Equivocal**	**Negative**	**Total**
VIDAS 3	**Positive**	111	0	0	111
	Equivocal	3	8	1	12
	Negative	0	1	96	97
	Total	114	9	97	220

Associated percent agreements and their 95% two-sided exact confidence interval are calculated in the table below:

Category	**Samples of interest/Total**	**Percent Agreement 2-sided 95% CI**
Negative	96/97	99% [94.4;99.8] %
Positive	111/114	97.4% [92.5;99.1] %

b. Matrix comparison:

Previously reviewed in k080766.

3. Clinical studies: VIDAS RUB IgG

a. Clinical Sensitivity:

Not Applicable.

b. Clinical specificity:

Not Applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

CDC low-titer rubella antibody standard results:
Vials of CDC low-titer reference standard were reconstituted with distilled water as preconized by CDC and then pooled as MSN (Master Stock Neat). According to the CDC information, the theoretical dose of the neat solution was 21 IU/mL. A ½ dilution solution was then prepared from the MSN solution and had an expected dose at 10.5 IU/mL.

The neat and 1/2 dilutions solutions of the CDC low titer standard (MSN & MS1/2 solutions) were then in triplicate in the same run on the VIDAS and the VIDAS 3 instruments using the same VIDAS RUB IgG reagent lot.

The mean result (IU/mL) obtained with the neat and 1/2 dilutions of the CDC low-titer standard and the difference in % compared to the theoretical/expected concentration of CDC low-titer standard were calculated for the VIDAS and the VIDAS 3:

- For VIDAS 3, the mean value of the neat and ½ dilution was respectively -11.0% and -11.4% compared to the theoretical concentration.
- For VIDAS, the mean value of the neat and ½ dilution was respectively -15.7% and -7.6% compared to the theoretical concentration.

CDC reference panel testing, data analysis and results:
The CDC reference panel consisted of 100 specimens, 50 pairs of sera titered by Hem agglutination (9 negative sera resulting in 18 negative specimens and 41 positive sera resulting in 82 positive specimens). A single replicate of each of the 100 CDC reference panel samples was tested on the VIDAS and the VIDAS 3 instruments using the same VIDAS RUB IgG reagent lot.

The number of positive and negative sera detected are identical between VIDAS and VIDAS 3 systems: The VIDAS RUB IgG (RBG) assay identified 80/82 (97.6%) positive tests on 82 positive sera and 18/18 (100%) negative tests on 18 negative sera. One of the pairs of HI positive sera were reported as VIDAS equivocal (both results).

4. Clinical cut-off**:** VIDAS RUB IgG

   Not Applicable.

5. Expected values/Reference range: VIDAS RUB IgG

   Previously reviewed in k080766.

IV. VIDAS TOXO M

1. Analytical performance: VIDAS TOXO M

a. *Precision/Reproducibility:*

Precision

Four serum samples were tested in 3 replicates twice a day (2 runs per day) over 6 days on 1 reagent lot using 3 instruments at 1 site (N = 108). The repeatability (within-run precision), between-run, between-day, between calibration, between instrument, total between calibration, and total between instrument precision were calculated according to CLSI EP5-A2. *"Evaluation of Precision Performance of Quantitative Measurement Methods"*. The results were as follows:

	Sample 1		**Sample 2**		**Sample 3**		**Sample 4**	
	N = 108		**N = 108**		**N = 108**		**N = 108**	
	Mean Index 0.47		**Mean Index 0.60**		**Mean Index 0.79**		**Mean Index 1.07**	
	SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Within-RUN (Repeatability)	0.01	3.0	0.02	3.0	0.02	2.7	0.03	2.7
Between-RUN	0.00	0.0	0.00	0.7	0.00	0.0	0.00	0.0
Between-DAY	0.00	0.0	0.00	0.5	0.01	0.9	0.01	1.1
Between-CALIBRATION	0.01	2.4	0.00	0.0	0.01	0.8	0.00	0.0
Between-INSTRUMENT	0.00	0.0	0.00	0.8	0.01	0.7	0.02	1.7
Total Between-CALIBRATION	0.02	3.9	0.02	3.2	0.02	3.0	0.03	2.9
Total Between-INSTRUMENT	0.02	3.9	0.02	3.3	0.02	3.1	0.04	3.4

b. *Linearity/assay reportable range:*

Not applicable.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Not applicable.

d. *Detection limit:*

Not applicable.

e. Analytical specificity:

Previously reviewed in k923166.

f. Assay cut-off:

Not applicable.

2. Comparison studies: VIDAS TOXO M

a. Method comparison with predicate device:

Method Comparison
A study was conducted to verify the correlation of the VIDAS TOXO IgM assay on the VIDAS 3 to the VIDAS TOXO IgM assay on the VIDAS. One reagent lot, one of each instrument and 198 serum samples were used, and results were evaluated according to CLSI EP9. *"Method Comparison and Bias Estimation Using Patient Samples"*. The results were as follows:

Contingency table:

		VIDAS			
		Positive	**Equivocal**	**Negative**	**Total**
VIDAS 3	**Positive**	93	0	0	93
	Equivocal	2	4	0	6
	Negative	1	0	98	99
	Total	96	4	98	198

Associated percent agreements and their 95% two-sided score confidence intervals are calculated in the table below :

Category	**Samples of interest/Total**	**Percent Agreement 2-sided 95% CI**
Negative	98/98	100% [96.2;100.0] %
Positive	93/96	96.9% [91.2;98.9] %

b. Matrix comparison:

Previously reviewed in k923166.

3. Clinical studies: VIDAS TOXO M

   a. Clinical Sensitivity:

   Not applicable.

   b. Clinical specificity:

   Not applicable.

   c. Other clinical supportive data (when a. and b. are not applicable):

   Not applicable.

4. Clinical cut-off: VIDAS TOXO M

   Not applicable.

5. Expected values/Reference range: VIDAS TOXO M

   Previously reviewed in k923166.

V. VIDAS Human Chorionic Gonadotropin

1. Analytical performance: VIDAS Human Chorionic Gonadotropin

   a. Precision/Reproducibility:

   Precision
   Six natural human serum sample pools were tested in duplicate (2 replicates) twice a day (2 runs per day) over six days using three VIDAS 3 analyzers (N = 72). The repeatability (within-run precision), between- run, between-day, and total between instrument precision were calculated according to CLSI EP5-A2. *"Evaluation of Precision Performance of Quantitative Measurement Methods"*. The precision results were as follows:

	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5		Sample 6	
	N = 72		N = 72		N = 72		N = 72		N = 72		N = 72	
	Mean (mIU/mL) 4.46		Mean (mIU/mL) 6.46		Mean (mIU/mL) 9.48		Mean (mIU/mL) 74.43		Mean (mIU/mL) 311.52		Mean (mIU/mL) 1109.32	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Within-run	0.30	6.7	0.35	5.4	0.41	4.4	3.16	4.2	12.48	4.0	56.36	5.1

Between-run	0.12	2.7	0.20	3.1	0.13	1.4	0.73	1.0	0.00	0.0	0.00	0.0
Between-day	0.00	0.0	0.00	0.0	0.19	2.0	0.32	0.4	5.75	1.8	0.00	0.0
Total Between-instrument	0.34	7.6	0.48	7.5	0.54	5.7	4.02	5.4	14.84	4.8	65.16	5.9

b. Linearity/assay reportable range:

Linearity

Human serum sample pools were serially diluted into a total of 11 samples and tested in triplicate in order to evaluate the linearity according to CLSI EP06-A "*Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach*". The VIDAS HCG assay on VIDAS 3 is linear across the measuring range 2 - 1500 mIU/mL

Linear regression analysis between the expected values and the observed values generated the following equation: $y= 1.060x – 0.109$, $R^2 = 0.9977$ (Sample range tested from 1.95 - 1607.99 mIU/mL)

An additional study was performed to assess the automated dilution capability of the VIDAS 3 by comparing doses obtained with automated dilution on VIDAS 3 to theoretical doses estimated using manual dilutions. The study was reviewed and found to be acceptable.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Previously reviewed in k921302

d. Detection limit:

The detection limits of the VIDAS HCG assay on the VIDAS 3 were evaluated per CLSI EP17-A2 "*Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline, Second Edition*". For LoB determination, 6 blank samples were each tested in 4 replicates in a single run per day for 4 days with 1 VIDAS 3 instrument and 2 reagent lots. For LoD/LoQ determinations, 6 low-level samples were each tested in 6 replicates, 2 runs per day, for 5 days, with 1 VIDAS 3 instrument and 2 reagent lots. The LoB, LoD and LoQ determinations were based consequently on 912 results, including 192 results from blank samples and 720 results from low-level samples both reagent lots combined. The LoB, LoD, LoQ of the VIDAS HCG assay on the VIDAS 3 are as follows: LoB = 0.242 mIU/mL; LoD = 0.571 mIU/mL; LoQ = 1.280 mIU/mL.

The sponsor claimed that the LoQ is 1.28 mIU/mL and demonstrated that recovery is within ≤ 10% bias and %CV is <20% at the LoQ.

hCG assay has a measuring range of 2-1500 mIU/mL

e. Analytical specificity:

Previously reviewed in k921302.

f. Assay cut-off:

Not applicable.

2. Comparison studies: VIDAS Human Chorionic Gonadotropin

a. Method comparison with predicate device:

Method Comparison
A method comparison study was conducted to verify the correlation of the VIDAS HCG assay on the VIDAS 3 analyzer to the VIDAS HCG assay on the VIDAS analyzer. 113 serum samples were analyzed in the study using one singlet set of data from the candidate device. Samples covered the range of 3.12 to 1485.83 mIU/L and results were evaluated according to CLSI EP9. *"Method Comparison and Bias Estimation Using Patient Samples"*. The regression results were as follows:

Analysis	N	Slope, (with CI)	Intercept, (with CI)	r, (with CI)
Weighted Deming	113	0.9265 (0.9043, 0.9488)	0.0828 (-0.1242, 0.2898)	0.9848 (0.9779, 0.9895)
Passing Bablok	113	0.9378 (0.9103, 0.9654)	0.0041 (-0.2236, 0.2319)	0.9848 (0.9779, 0.9895)

b. Matrix comparison:

Acceptable sample types for these assays include serum and plasma. Previously established in k921302.

3. Clinical studies: VIDAS Human Chorionic Gonadotropin

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off**:** VIDAS Human Chorionic Gonadotropin

Not applicable.

5. Expected values/Reference range: VIDAS Human Chorionic Gonadotropin

Population	N	Normal range
Women	204	< 5 mIU/mL
Menopausal women	268	< 10 mIU/mL

Reference range previously established in k921302

VI. VIDAS T4

1. Analytical performance: VIDAS T4

a. Precision/Reproducibility:

Precision
Five natural human serum sample pools were tested in duplicate (2 replicates) twice a day (2 runs per day) over six days using three VIDAS 3 analyzers (N = 72). The repeatability (within-run precision), between- run, between-day, and total between instrument precision were calculated according to CLSI EP5-A2. *"Evaluation of Precision Performance of Quantitative Measurement Methods"*. The precision results were as follows:

	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5	
	N = 72		N = 72		N = 72		N = 72		N = 72	
	Mean (nmol/L) 12.8		Mean (nmol/L) 35.14		Mean (nmol/L) 63.60		Mean (nmol/L) 121.99		Mean (nmol/L) 227.17	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Within-run	1.17	9.1	1.54	4.4	1.88	3.0	4.24	3.5	12.46	5.5
Between-run	0.00	0.0	0.00	0.0	0.62	1.0	1.53	1.3	0.00	0.0
Between-day	0.76	6.0	0.00	0.0	0.34	0.5	0.00	0.0	4.74	2.1

Total Between-instrument	1.48	11.6	1.80	5.1	2.47	3.9	4.66	3.8	13.96	6.1

b. Linearity/assay reportable range:

Linearity
Human serum sample pool was serially diluted into a total of 11 samples and tested in triplicate in order to evaluate the linearity according to CLSI EP06-A "*Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach*". The VIDAS T4 assay on VIDAS 3 is linear across the measuring range 6 - 320 nmol/L.

Linear regression analysis between the expected values and the observed values generated the following equation: $y= 0.9343x + 0.3462$, $R^2 = 0.9965$ (Sample range tested from 5.27 – 372.87 nmol/L)

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Previously reviewed in k926393.

d. Detection limit:

The detection limits of the VIDAS T4 assay on the VIDAS 3 were evaluated per CLSI EP17-A2 "*Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline, Second Edition*". For LoB determination, 6 blank samples were each tested in 4 replicates in a single run per day for 4 days with 1 VIDAS 3 instrument and 2 reagent lots. For LoD/LoQ determinations, 6 low-level samples were each tested in 6 replicates, 2 runs per day, for 5 days, with 1 VIDAS 3 instrument and 2 assay lots. The LoB, LoD and LoQ determinations were based consequently on 912 results, including 192 results from blank samples and 720 results from low level samples both reagent lots combined. The LoB, LoD, LoQ of the VIDAS T4 assay on the VIDAS 3 are as follows:
LoB = 1.596 nmol/L; LoD = 3.749 nmol/L; LoQ = 6.216 nmol/L.

The sponsor defines the LoQ value as within-laboratory precision of ≤20% CV.

T4 assay has a measuring range of 6 - 320 nmol/L.

e. Analytical specificity:

Previously reviewed in k926393.

f. Assay cut-off:

Not applicable.

2. Comparison studies: VIDAS T4

a. Method comparison with predicate device:

Method Comparison
A method comparison study was conducted to verify the correlation of the VIDAS T4 assay on the VIDAS 3 analyzer to the VIDAS T4 assay on the VIDAS analyzer. 105 serum samples (5 spiked) were analyzed in the study using one singlet set of data from the candidate device. Samples covered the range of 10.07 to 306.34 nmol/L. Results were evaluated according to CLSI EP9. *"Method Comparison and Bias Estimation Using Patient Samples"*. The regression results were as follows:

Analysis	N	Slope	Intercept	Correlation coefficient
Weighted Deming	105	0.9547	-0.6860	0.9866
Passing Bablok	105	0.9523	-0.4397	0.9866

b. Matrix comparison:

Acceptable sample types for these assays include serum and plasma. Previously established in k926393.

3. Clinical studies: VIDAS T4

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off: VIDAS T4

Not applicable.

5. Expected values/Reference range: VIDAS T4
Expected range: 60-120 nmol/L

Reference range previously established in k926393.

VII. VIDAS Testosterone

1. Analytical performance: VIDAS Testosterone

a. Precision/Reproducibility:

Precision

Five natural human serum sample pools were tested in duplicate (2 replicates) twice a day (2 runs per day) over 6 days using three VIDAS 3 analyzers at 1 site (N = 72). The repeatability (within-run precision), between- run, between-day, between calibration, between instrument, total between calibration, and total between instrument precision were calculated according to CLSI EP5-A2. *"Evaluation of Precision Performance of Quantitative Measurement Methods"*. The precision results were as follows:

	Sample 1		Sample 2		Sample 3		Sample 4		Sample 5	
	N = 72		N = 72		N = 72		N = 72		N = 72	
	Mean (ng/mL) 0.32		Mean (ng/mL) 1.8		Mean (ng/mL) 3.22		Mean (ng/mL) 5.17		Mean (ng/mL) 9.04	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Within-run	0.03	10.6	0.11	6.2	0.17	5.2	0.22	4.3	0.41	4.6
Between-run	0.01	4.5	0.08	4.2	0.10	3.2	0.00	0.0	0.12	1.3
Between-day	0.00	0.0	0.00	0.0	0.00	0.0	0.07	1.4	0.00	0.0
Total Between-instrument	0.06	18.1	0.18	10.2	0.25	7.8	0.36	7.0	0.60	6.6

b. Linearity/assay reportable range:

Linearity

Human serum sample pools were serially diluted into a total of 11 samples and tested in triplicate in order to evaluate the linearity according to CLSI EP06-A "*Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach*". The VIDAS Testosterone assay on VIDAS 3 is linear across the measuring range 0.1- 13 ng/mL.

Linear regression analysis between the expected values and the observed values generated the following equation: $y= 1.042x + 0.004$, $R^2 = 0.9974$ (Sample range tested from 0.064 – 15.832 ng/mL)

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Previously reviewed in k021326.

d. Detection limit:

The detection limits of the VIDAS Testosterone assay on the VIDAS 3 were evaluated per CLSI EP17- A2 "*Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline, Second Edition*". For LoB determination, 6 blank samples were each tested in 4 replicates in a single run per day for 4 days with 1 VIDAS 3 instrument and 2 reagent lots. For LoD/LoQ determinations, 6 low-level samples were each tested in 6 replicates, 2 runs per day, for 5 days, with 1 VIDAS 3 instrument and 2 reagent lots. The LoB, LoD and LoQ determinations were based consequently on 912 results, including 192 results from blank samples and 720 results from low-level samples both reagent lots combined. The LoB, LoD, LoQ of the VIDAS Testosterone assay on the VIDAS 3 are as follows: LoB = 0.018 ng/mL; LoD = 0.035 ng/mL; LoQ = 0.088 ng/mL.

The sponsor defines the LoQ value as within-laboratory precision of ≤20% CV.

Testosterone assay has a measuring range of 0.1-13 ng/mL

e. Analytical specificity:

Previously reviewed in k021326.

f. Assay cut-off:

Not applicable.

2. Comparison studies: VIDAS Testosterone

a. Method comparison with predicate device:

Method Comparison

A method comparison study was conducted to verify the correlation of the VIDAS Testosterone assay on the VIDAS 3 analyzer to the VIDAS Testosterone assay on the VIDAS analyzer. 172 serum samples were analyzed in the study using one singlet set of data from the candidate device. Samples covered the range of 0.11 to 12.61 ng/mL and results were evaluated according to CLSI EP9. *"Method Comparison and Bias Estimation Using Patient Samples"*. The regression results were as follows:

Analysis	N	Slope	Intercept	Correlation coefficient
Weighted Deming	172	0.9799	0.0030	0.9957
Passing Bablok	172	0.9751	0.0085	0.9957

b. Matrix comparison:

Acceptable sample types for these assays include serum and plasma. Previously established in k021326.

3. Clinical studies: VIDAS Testosterone

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off: VIDAS Testosterone

Not applicable.

5. Expected values/Reference range: VIDAS Testosterone

Cyclic women:	0.1-0.9 ng/mL
Men:	3.0-10.6 ng/mL

Reference range previously established in k021326

VIII. VIDAS TSH

1. Analytical performance: VIDAS TSH

a. Precision/Reproducibility:

Precision
Six natural human serum sample pools were tested in duplicate (2 replicates) twice a day (2 runs per day) over 6 days using three VIDAS 3 analyers (N = 72). The repeatability (within-run precision), between- run, between-day, and total between instrument precision were calculated according to CLSI EP5-A2. *"Evaluation of Precision Performance of Quantitative Measurement Methods"*. The precision results were as follows:

	Sample 1 N = 72 Mean (µIU/mL) 0.1		Sample 2 N = 72 Mean (µIU/mL) 0.26		Sample 3 N = 72 Mean (µIU/mL) 2.45		Sample 4 N = 72 Mean (µIU/mL) 5.1		Sample 5 N = 72 Mean (µIU/mL) 10.32		Sample 6 N = 72 Mean (µIU/mL) 35.01	
	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Within-run	0.00	5.1	0.01	2.5	0.05	2.0	0.10	2.0	0.20	2.0	0.70	2.0
Between-run	0.00	1.7	0.00	1.2	0.02	1.0	0.08	1.6	0.13	1.3	0.00	0.0
Between-day	0.00	0.0	0.00	1.7	0.02	0.8	0.00	0.0	0.00	0.0	0.19	0.5
Total Between-instrument	0.01	5.5	0.01	3.4	0.07	2.8	0.15	3.0	0.29	2.8	1.04	3.0

b. Linearity/assay reportable range:

Linearity
Human sample pools were serially diluted into a total of 11 samples and tested in triplicate in order to evaluate the linearity according to CLSI EP06-A "*Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach*". The VIDAS TSH assay on VIDAS 3 is linear across the measuring range 0.05 to 57 µIU/mL.

Linear regression analysis between the expected values and the observed values

generated the following equation: y= 1.091x - 0.004, R^2 = 0.9965 (Sample range tested from 0.047 - 56.9 µIU/mL)

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Previously reviewed in k921816.

d. *Detection limit:*

The detection limits of the VIDAS TSH assay on the VIDAS 3 were evaluated per CLSI EP17-A2 "*Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline, Second Edition*". For LoB determination, 6 blank samples were each tested in 4 replicates in a single run per day for 4 days with 1 VIDAS 3 instrument and 2 reagent lots. For LoD/LoQ determinations, 6 low-level samples were each tested in 6 replicates, 2 runs per day, for 5 days, with 1 VIDAS 3 instrument and 2 reagent lots. The LoB, LoD and LoQ determinations were based on 912 results, including 192 results from blank samples and 720 results from low-level samples both reagent lots combined. The LoB, LoD, LoQ of the VIDAS TSH assay on the VIDAS 3 are as follows: LoB = 0.019 µIU/mL; LoD = 0.028 µIU/mL; LoQ = 0.05 µIU/mL.

The sponsor defines the LoQ value as within-laboratory precision of ≤20% CV.

TSH assay has a measuring range of 0.05 - 57 µIU/mL

e. *Analytical specificity:*

Previously reviewed in k921816.

f. *Assay cut-off:*

Not applicable.

2. Comparison studies: VIDAS TSH

a. *Method comparison with predicate device:*

Method Comparison
A method comparison study was conducted to verify the correlation of the VIDAS TSH assay on the VIDAS 3 analyzer to the VIDAS TSH assay on the VIDAS analyzer. 179 serum samples were analyzed in the study using one singlet set of data from the candidate device. Samples covered the range of 0.050 to 55.73 µIU/mL and results were evaluated according to CLSI EP9. *"Method Comparison and Bias Estimation Using Patient Samples"*. The regression results were as follows:

Analysis	N	Slope	Intercept	Correlation coefficient
Weighted Deming	179	1.0034	0.0042	0.9984
Passing Bablok	179	1.0028	-0.0001	0.9984

b. Matrix comparison:

Acceptable sample types for these assays include serum and plasma. Previously established in k921816.

3. Clinical studies: VIDAS TSH

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off: VIDAS TSH

Not applicable.

5. Expected values/Reference range: VIDAS TSH

Sample	Expected Result
Euthyroid	0.25-5µIU/mL
Hyperthyroid	<0.15 µIU/mL
Hypothyroid	>7 µIU/mL

Reference range previously established in k921816.

The labeling recommends that each laboratory establish its own reference values.

IX. VIDAS D-Dimer Exclusion II

1. Analytical performance: VIDAS D-Dimer Exclusion II

a. Precision/Reproducibility:

Precision

Four plasma samples covering the analytical measurement range of the VIDAS® D-Dimer Exclusion II™ assay were tested in duplicate, twice a day, over six days. Testing was performed using one reagent lot across three instruments at one testing site. A total of 144 measurements with 72 measurements per type of system (VIDAS and VIDAS 3) were generated for each sample. The precision results on the VIDAS 3 system are summarized as follows:

Precision Data Summary										
Sample	N	Mean (ng/mL)	Within-Run		Between-Run		Between-Day		Total Between-Instrument	
			SD (ng/mL)	%CV	SD (ng/mL)	%CV	SD (ng/mL)	%CV	SD (ng/mL)	%CV
1	72	73.73	2.36	3.2	1.08	1.5	0.00	0.0	2.96	4.0
2	72	243.06	6.66	2.7	0.00	0.0	0.45	0.2	7.47	3.1
3	72	472.14	10.04	2.1	0.00	0.0	0.00	0.0	12.68	2.7
4	72	6939.36	114.20	1.6	59.97	0.9	0.00	0.0	190.14	2.7

b. Linearity/assay reportable range:

Linearity

Linearity was evaluated according to CLSI EP06-A "*Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach*". Two high concentration samples were serially diluted into 11 and 15 samples, respectively, and tested in three runs with one replicate per run on the VIDAS 3 system. At each tested concentration, deviation from linearity was within the predetermined acceptance criterion of ±12%. The VIDAS® D-Dimer Exclusion II™ assay on the VIDAS 3 system was determined to be linear across the measuring range, 45–10000 ng/mL.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Not applicable

d. Detection limit:

The detection limits of the VIDAS® D-Dimer Exclusion II™ assay on the VIDAS 3 instrument were evaluated per CLSI EP17-A2 "*Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline, Second Edition*". For LoB determination, six blank samples were each tested in four replicates in a single run per day. Testing was performed over four days with one VIDAS 3 instrument and two assay reagent lots. For LoD/LoQ determinations, six low-level samples were each tested in six replicates per run, two runs per day. Testing was completed over five days with one VIDAS 3 instrument and two assay reagent lots. The resulting LoB, LoD, and LoQ of the VIDAS® D-Dimer Exclusion II™ assay on the VIDAS 3 are summarized in the table below:

VIDAS 3 Detection Limits	
LoB	10.56 ng/mL
LoD	16.25 ng/mL
LoQ	17.23 ng/mL

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies: VIDAS D-Dimer Exclusion II

a. Method comparison with predicate device:

Method Comparison
A study was conducted to verify the agreement of the VIDAS® D-Dimer Exclusion II™ assay on the VIDAS 3 instrument with the same assay on the VIDAS® instrument. A total of 221 human plasma samples (209 patient samples and 12 contrived samples) were tested in singlicate with both systems. Sample concentrations covered the ranges of 61.15 ng/mL to 8976.31 ng/mL Fibrinogen Equivalent Unit (FEU) and 67.52 ng/mL to 9380.79 ng/mL FEU for the VIDAS 3 and VIDAS systems, respectively. Two samples with observed results outside the assay measuring range were excluded from the data analysis. Both Passing & Bablok regression and Weighted Deming regression were performed between the results observed on the VIDAS 3 and the VIDAS systems and are summarized in the table below:

Method Comparison Summary, Regression				
Analysis Method	N	Slope	Intercept	Correlation Coefficient
Weighted Deming	219	0.9481	2.0974	0.9954
Passing & Bablok	219	0.9394	5.1190	0.9954

Difference estimates between the VIDAS 3 and VIDAS systems and their confidence intervals are summarized as follows:

Method Comparison Summary, Difference Estimates			
Analysis Method	Sample Level (ng/mL)	Bias	95% CI
Weighted Deming	500	-4.8%	[-6.0%; -3.5%]
	5000	-5.2%	[-6.6%; -3.7%]
Passing & Bablok	500	-5.0%	[-6.0%; -4.1%]
	5000	-6.0%	[-7.6%; -4.3%]

b. Matrix comparison:

Not applicable

3. Clinical studies: VIDAS D-Dimer Exclusion II

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off**:** VIDAS D-Dimer Exclusion II

Not applicable

5. Expected values/Reference range: VIDAS D-Dimer Exclusion II

Not applicable

N. Instrument Name:

VIDAS 3

O. System Descriptions:

1. Modes of Operation:

Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

Yes ___X_____ or No _____

Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

Yes _____ or No ___X_____

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   Yes ___X_____ or No _____

3. Specimen Identification:

   Manual entry, Bar Code, or LIS

4. Specimen Sampling and Handling:

   Automated or manual sample dilution, automated sample handling

5. Calibration:

   System auto-calibrates regularly. There are also assay calibrators that must be run with each new kit.

6. Quality Control:

   Controls need to be run with each assay (kit controls, internal controls and external controls).

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

VIDAS HCG Assay
A carry-over study was performed using a low level sample pool with a concentration between 2 and 3mIU/mL and a high positive spiked sample pool with an analyte concentration of 1,000,000 mIU/mL. The high hCG positive sample was tested with the hCG batch negative sample and carry-over analyte negative samples during 7 runs on three VIDAS 3 analyzers. Results were found to be acceptable.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.