VIDAS® HCG (HCG)

℞ only IVD

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 to aid in the early detection of pregnancy.

SUMMARY AND EXPLANATION OF THE TEST

The human Chorionic Gonadotropin (hCG) is a glycoprotein with a molecular weight of 40,000 daltons. Two polypeptide subunits, alpha and beta, form hCG. The hCG alpha subunit, composed of 92 amino acids, contains the amino acid sequence identical to that of the other three glycoprotein hormones: LH, FSH, and TSH. The beta subunit, composed of 145 amino acids and 5 oligosaccharidic groups, contains a unique amino acid sequence which gives biological and immunological specificity to hCG.

The appearance of hCG in serum is evident shortly after conception. The level of hCG in serum will steadily increase and reach a maximum during the first three months of pregnancy. The level then decreases until the 16th week of pregnancy where it stabilizes until pregnancy term. The physiologic function of hCG in pregnancy is to maintain the gestational body and to foster progesterone and estrogen production during the first three months of pregnancy. HCG also aids in the differentiation of the fetal genital tractus and protects the mother's immune system from external attacks.

Quantitative measurement of hCG in serum is widely used in the early detection and confirmation of pregnancy.

PRINCIPLE OF THE PROCEDURE

The VIDAS® HCG (HCG) 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-hCG antibodies. The VIDAS HCG (HCG) 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-hCG antibody conjugated with alkaline phosphatase. The sample/conjugate mixture is cycled in and out of the SPR and the hCG 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 hCG concentration present in the sample.

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

KIT COMPOSITION (60 tests):

60 HCG Reagent Strips	STR	Ready to use.
60 HCG SPRs (2 x 30)	SPR®	Ready to use. SPRs coated with mouse monoclonal anti-hCG antibodies.
HCG Control (lyophilized) (1 x 2 mL)	C1	Reconstitute with 2 mL distilled water. Wait 5 to 10 minutes. Mix. Stable after reconstitution for 14 days at 2-8°C or until expiration date on kit at -25 ± 6°C. Five freeze/thaw cycles are possible. Human serum* with human hCG and 0.1g/L sodium merthiolate. MLE data indicate the confidence interval in mIU/mL ("Control C1 Dose Value Range").
HCG Calibrator (lyophilized) (2 x 2 mL)	S1	Reconstitute with 2 mL distilled water. Wait 5 to 10 minutes. Mix. Stable after reconstitution for 14 days at 2-8°C or until expiration date on kit at -25 ± 6°C. Five freeze/thaw cycles are possible. Calf serum with human hCG and 0.1g/L sodium merthiolate. MLE data indicate the dose value in mIU/mL (1st IRP 75/537) ("Calibrator (S1) Dose Value") and the confidence interval in "Relative Fluorescence Value ("Calibrator (S1) RFV Range).
HCG Diluent (liquid) (2 x 25 mL)	R1	Ready to use. Calf serum with 1 g/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 barcodes printed on the box label.		
1 Package Insert provided in the kit 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 monoclonal anti-hCG immunoglobulins (mouse). Each SPR is identified by the "HCG" 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 HCG Reagent Strip

Wells	Reagents
1	Sample well
2-3-4	Empty wells
5	Conjugate: Mouse monoclonal anti-hCG antibodies conjugated to alkaline phosphatase with 1 g/L sodium azide (600 µL).
6-7	Wash buffer: Sodium phosphate (0.01 mol/L, pH 7.4) with 1 g/L sodium azide (600 µL)
8	Wash buffer: diethanolamine DEA* (1.1 mol/L or 11.5%) pH 9.8 + 1 g/L sodium azide (600 µL).
9	Empty well
10	Reading cuvette with Substrate: 4-methylumbelliferyl 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.

** Signal Word: **DANGER**

Hazard statement

H318 : Causes serious eye damage.

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.

For further information, refer to the Safety Data Sheet.

MATERIALS REQUIRED BUT NOT PROVIDED

- Pipette with disposable tips to dispense 2 mL and 100 µL.
- Powderless disposable gloves.
- For other specific materials, please refer to the Instrument Operator's Manual.
- Instrument of the VIDAS family: VIDAS, miniVIDAS or VIDAS 3.

WARNINGS AND PRECAUTIONS

- **For *in vitro* diagnostic use.**
- **Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner.**
- **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).**
- 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.
- 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).
- Do not mix reagents or disposables from different lots.
- Kit reagents contain 1 g/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.
- The wash buffer (well 8) contains a harmful agent (11.5% diethanolamine). Refer to the hazard statements "H" and the precautionary statements "P" above.
- The 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® HCG (HCG) 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 EDTA or heparin anticoagulant). 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 samples at -25 ± 6 °C. Avoid repeated cycles of freezing and thawing. If necessary, clarify samples by centrifugation.

INSTRUCTIONS FOR USE

For complete instructions, see the Operator'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.
It is possible to enter MLE data **manually or automatically** depending on the instrument (refer to the Operator's Manual).

Calibration

Calibration, using the calibrator provided in the kit, must be performed each time a new lot of reagents is opened, 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 2-8°C.
2. Allow components to reach room temperature (approximately 30 minutes).
3. Use one "HCG" strip and one "HCG" 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 "HCG" code on the instrument. The calibrator must be identified by "S1", and tested in **duplicate**. If the control is to be tested, it should be identified by "C1".
5. If needed label the "HCG" Reagent Strips with the appropriate sample identification numbers.
6. Mix the Calibrator, Control and sample 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 100 µL.**
8. Insert the "HCG" 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 30 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® HCG (HCG) kit.
This control must be performed immediately after opening a new kit to ensure that 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.
The acceptable range of results for the VIDAS HCG (HCG) assay is 2 mIU/mL to 1500 mIU/mL. Samples with concentrations greater than 1500 mIU/mL must be diluted by 1/20 (1 volume of sample and 19 volumes of diluent R1) or 1/200 (1 volume of sample and 199 volumes of diluent R1) in VIDAS HCG (HCG) diluent R1. 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 hCG 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 hCG concentration

LIMITATION OF THE TEST

Elevated serum hCG levels are seen in patients with certain trophoblastic diseases, as well as in pregnancy. As stated in the Intended Use, the VIDAS HCG (HCG) assay is only for use to aid in the early detection of pregnancy, not for use in monitoring tumor activity.

PERFORMANCE DATA

Immunological Specificity

The cross-reactivity percentage is the ratio between the compound concentration to be tested and the hCG concentration to be tested at signal of 1000 RFV. No cross-reactivity in the VIDAS HCG (HCG) assay was observed with the substances tested.

Tested components	Cross-reactivity percentage
LH (SCRIPPS ref. L0815-lot n°399711)	0.10
FSH (SCRIPPS ref. F0615-lot n°312711)	0.10
TSH (SCRIPPS ref. T0115-lot n°148911)	< 0.07
hCG free alpha subunit (SCRIPPS ref. C0814-lot n°255091)	0.31
hCG free beta subunit (SCRIPPS ref. C0914-lot n°232812)	2.3
hCG (SCRIPPS ref. C0714-lot n°210164)	100

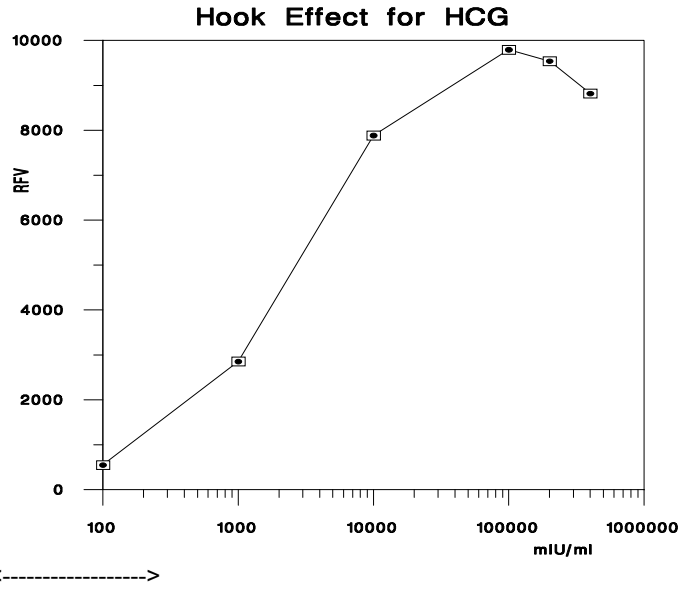
Immunological interference was tested by adding 10,000 mIU/mL of LH or 12,500 mIU/mL of FSH to a sample containing 1356 mIU/mL of hCG. No interference in the VIDAS HCG (HCG) assay was observed with either of the substances tested.

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 HCG (HCG) assay on VIDAS/miniVIDAS is 2 mIU/mL.
The detection limits (Limit of Blank LoB, Limit of Detection LoD, Limit of Quantification LoQ) the VIDAS HCG assay on VIDAS 3 were evaluated per CLSI EP17-A2 and were: LoB = 0.242 mIU/mL; LoD = 0.571 mIU/mL; LoQ = 1.280 mIU/mL.

Hook Effect

The Hook effect was tested using hCG concentrations up to 400,000 mIU/mL. As seen in the graph below the signal no longer increases at concentrations greater than 100,000 mIU/mL. However, all concentrations tested between 1,500 and 400,000 mIU/mL produced printouts with the statement “>1,500 mIU/mL OFF CURVE”.



Linearity – VIDAS 3

Three sample pools were serially diluted into a total of 11 samples in order to evaluate the linearity according to CLSI EP06-A. The VIDAS HCG assay on VIDAS 3 is linear across the measuring range 2 - 1500 mIU/mL.

PRECISION/REPRODUCIBILITY – VIDAS/MINIVIDAS

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 mIU/mL)	16.6	71.8	257.0	334.0	1211.0
% CV	6.8	4.3	4.6	4.8	5.4

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 (mIU/mL)	17.4	71.4	253.0	334.0	1152.0
% CV	8.7	5.1	4.3	4.8	5.0

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 (mIU/mL)	15.6	71.0	253.0	338.0	1126.0
% CV	9.4	4.3	5.3	5.7	5.3

PRECISION/REPRODUCIBILITY (VIDAS 3)

Six serum samples 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 results were calculated according to CLSI EP5-A2 and 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 (Repeatability)	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-CALIBRATION	0.08	1.7	0.26	4.1	0.12	1.3	2.36	3.2	5.59	1.8	32.71	2.9
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

Three samples were diluted in VIDAS HCG (HCG) diluent and tested in singlet in 3 runs.

Sample	Dilution factor	Expected values (mIU/mL)	Measured values (mIU/mL)	Recovery percentage
1	1/1	239.0	239.0	100.0
	1/2	119.5	120.3	100.0
	1/4	59.8	59.2	99.0
	1/8	29.9	28.5	96.0
	1/16	15.0	14.0	94.0
	1/32	7.5	6.2	83.0
2	1/1	329.0	329.0	100.0
	1/2	164.8	163.7	99.0
	1/4	82.4	77.8	94.0
	1/8	41.2	39.2	95.0
	1/16	20.6	19.1	93.0
	1/32	10.3	8.4	81.0
3	1/1	1102.0	1102.0	100.0
	1/2	551.0	565.0	102.0
	1/4	275.5	279.0	101.0
	1/8	137.8	139.0	101.0
	1/16	68.9	71.6	104.0
	1/32	34.4	34.0	99.0

Dilution – VIDAS 3
Four samples (human serum pool) were tested on two VIDAS 3 systems using an automated dilution sequence and a manual dilution sequence. The average relative difference between the observed HCG concentration (automatic testing) and the estimated theoretical HCG concentration (manual testing) was estimated as: Relative diff. (%) = 100 X (Observed dose – Theoretical dose) / Theoretical dose. The global average relative difference observed per dilution ratio ranged from -3.1% to +9.4%.

Carry-over – VIDAS 3
One high HCG positive sample was tested with one HCG negative sample and one carry-over sample. The average concentration carry-over observed on VIDAS 3 and its 95% confidence interval were calculated and determined to be <0.5 PPM (parts per million).

RECOVERY TESTS

Three samples were spiked with known quantities of hCG and tested in singlet in 3 runs. The measured mean concentration compared to the expected mean concentration is shown below.

Sample	Amount Spiked (mIU/mL)	Expected mean concentration (mIU/mL)	Measured mean concentration (mIU/mL)	Mean recovery percentage
1	0	69.4	69.4	100.0
	10.0	79.4	77.4	97.5
	56.4	125.8	112.1	89.1
	103.0	172.4	169.9	98.3
	585.0	654.4	647.6	98.9
	1308.0	1377.4	1230.0	89.3
2	0	247.0	247.0	100.0
	10.0	257.0	263.0	102.3
	56.4	303.0	293.0	96.7
	103.0	350.0	361.0	103.0
	585.0	832.0	849.0	102.0
	1308.0	> 1500.0	1441.0	-----
3	0	336.0	336.0	100.0
	10.0	346.0	342.0	98.8
	56.4	392.4	440.0	112.1
	103.0	439.0	430.0	97.9
	585.0	921.0	932.0	101.2
	1308.0	> 1500.0	> 1500.0	-----

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	y = 0.95 ref. + 2.34	0.97
Tube with EDTA	y = 0.97 ref. - 0.92	0.99
Tube with heparin (lithium)	y = 0.96 ref. + 0.54	0.99
Tube with separating gel	y = 1.10 ref. - 1.54	0.99

There are no significant differences between the 5 methods of collection.

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
hCG (mIU/mL)	Pool 1	14.8	14.5	14.4	14.0
	Pool 2	233.0	232.0	244.0	247.0
	Pool 3	1071.0	1025.0	1039.0	1014.0

EDTA

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

		Amount of EDTA spiked (mg/mL)			
		0	1	5	10
hCG (mIU/mL)	Pool 1	14.8	15.9	13.6	14.3
	Pool 2	233.0	251.0	239.0	236.0
	Pool 3	1071.0	1068.0	1029.0	1028.0

This data indicates that EDTA or heparin plasma can be used in the VIDAS HCG (HCG) assay.

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 (umol/l)						
		0	15	30	60	150	210	300
hCG (mIU/mL)	Pool 1	17.0	16.8	18.4	18.8	17.7	17.3	16.5
	Pool 2	221.0	232.0	235.0	228.0	234.0	231.0	237.0
	Pool 3	984.0	1050.0	967.0	1054.0	1015.0	1045.0	1023.0

Turbidity

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
hCG (mIU/mL)	Pool 1	16.5	16.4	16.4	17.3	16.7
	Pool 2	254.0	240.0	240.0	240.0	233.0
	Pool 3	1029.0	1112.0	1026.0	1072.0	1021.0
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
hCG (mIU/mL)	Pool 1	16.3	16.4	16.0	16.4	15.4	17.0	16.9
	Pool 2	227.0	228.0	234.0	233.0	234.0	229.0	241.0
	Pool 3	983.0	1062.0	984.0	1071.0	1043.0	1032.0	1023.0

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

EXPECTED VALUES

The results are given mIU/mL (1st IRP 75/537). Among a population of healthy people, and not infected with tumorous pathologies; the following values have been found:

Population:	N =	Normal Range:
- women	204	< 5 mIU/mL
-menopausal women	268	< 10 mIU/mL

It is advisable for each laboratory to establish its own expected values on a well-defined population.

CORRELATION – VIDAS/MINIVIDAS

One hundred ninety-one specimens were tested at a clinical chemistry laboratory. Samples with hCG concentrations ranging from 0 mIU/mL to 80,000 mIU/mL were tested using the VIDAS® HCG (HCG) assay and a commercially available quantitative hCG EIA. A summary of the results is shown below.

# of Samples	Slope	Intercept	Correlation coefficient
191	1.092	208.87	0.99

CORRELATION – VIDAS 3

A study was conducted to verify the correlation of the VIDAS HCG assay on the VIDAS 3 to the VIDAS HCG assay on the VIDAS. One reagent lot, one of each instrument and 113 serum samples were used. The results were evaluated according to CLSI EP9, 95% Confidence Intervals (CI) were calculated, and were as follows:

# of Samples	Slope	Intercept	Correlation coefficient
113	0.9265 [0.9043, 0.9488]	0.0828 [-0.1242, 0.2898]	0.9848 [0.9779, 0.9895]

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

1. FEINSTEIN M.C., AKAR A., BLACKER C., LAHLOU N., PERNOT P., WEIZANI H. “hCG et ses sous-unités comme marqueurs tumoraux”. J. Steroid. Biochem. 1989, 33, n°4B, 7716775.
2. NORMAN R.J., BUCK R. H., DEMEDEIROS S.F., “Measurement of human chorionic gonadotrophin (hCG): indications and techniques for the clinical laboratory. Ann. Clin. Biochem., 1990, 27, 183-194.
3. ODELL W.D., GRIFFIN J. “Pulsatile secretion of chorionic gonadotropin during the normal menstrual cycle”. J. Clin. Endocrinol. Met., 1989, 69, 528-532.
4. OZTURK M. et al. “Physiological studies of human chorionic gonadotropin (hCG) aHCG and bHCG as measured by specific monoclonal immunodiametric assays”. Endocrinol., 1987, 120, 549-558.
5. PIERCE J. G., PARSONS T.F. “Glycoprotein hormones : structure and function”. Ann. Rev. Biochem., 1981, 50, 465-495.
6. SCHOLLER R. “Surveillance hormonale de la grossesse”. Encycl., Med., Chir., paris, Obstétrique, 5015 A 10, 11-1980.
7. SCHOLLER R., GERNASY G., AVIBDOR R., CASTANIER M. “Colloque sur les actualités en immunoanalyse”. Ed. Bergeret, 1987, 225-233. Bordeaux. 2-4 décembre 1987.
8. WASS M., MITCHELL D.C., BAGSHAWE K.D. “Human chorionic gonadotrophin”. In hormones in blood (edited by C.H. GRAY and V.H.T JAMES), Academic Press, 3rd edition (1983), 179-193.

INDEX OF SYMBOLS

Symbol	Meaning
REF	Catalog number
IVD	*In Vitro* Diagnostic Medical Device
Rx only	Caution: US Federal Law restricts this device to sale by or on the order of a licensed practitioner
	Manufacturer
	Temperature limit
	Use by date
LOT	Batch code
	Consult Instructions for Use
	Contains sufficient for <n> tests
	Date of manufacture

WARRANTY

bioMérieux, Inc. disclaims all warranties, express or implied, including any implied warranties of MERCHANTABILITY AND FITNESS FOR A PARTICULAR USE. bioMérieux shall not be liable for any incidental or consequential damages. IN NO EVENT SHALL BIOMERIEUX'S LIABILITY TO CUSTOMER UNDER ANY CLAIM EXCEED A REFUND OF THE AMOUNT PAID TO BIOMERIEUX FOR THE PRODUCT OR SERVICE WHICH IS THE SUBJECT OF THE CLAIM.

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

Note: *Minor typographical, grammar, and formatting changes are not included in the revision history.*

Release date	Part Number	Change Type	Change Summary
2015/07	13695D	Administrative	INDEX OF SYMBOLS REVISION HISTORY
		Technical	KIT COMPOSITION (60 tests) MATERIALS REQUIRED BUT NOT PROVIDED WARNINGS AND PRECAUTIONS LIMITATION OF THE TEST PERFORMANCE DATA

BIOMÉRIEUX

bioMérieux SA
376 Chemin de l'Orme
69280 Marcy-l'Etoile – France
673 620 399 RCS LYON
Tel. 33 (0)4 78 87 20 00
Fax 33 (0)4 78 87 20 90
www.biomerieux.com

Distributed by
bioMérieux, Inc.
100 Rodolphe Street
Durham, North Carolina 27712 - USA
www.biomerieux.com