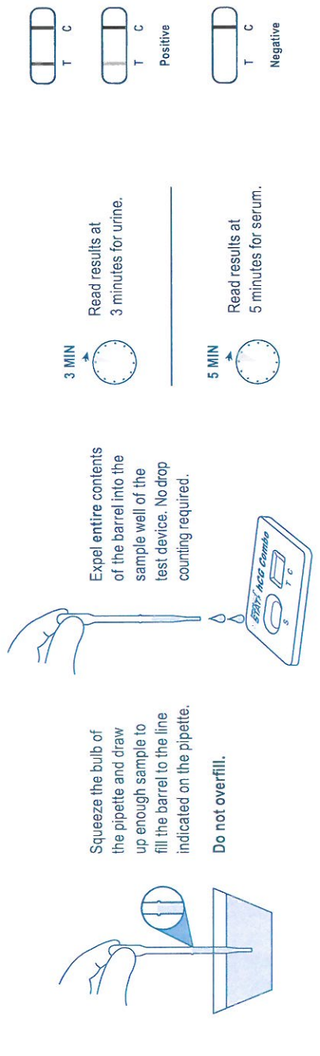
ImmunoCard STAT!® hCG Combo Test



Meridian Bioscience, Inc.

Rev. 3855-2, 06/15

ImmunoCard STAT!® hCG Combo Test

CLIA Complexity:
Urine - Waived
Serum - Non-Waived

REF 755425 IVD In vitro diagnostic medical device

INTENDED USE

The Immuno*Card* STAT! hCG Combo Test is a rapid immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum as an aid in the early determination of pregnancy. This test is for professional use in physicians' offices and clinical laboratories.

SUMMARY AND EXPLANATION OF THE TEST

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta.[1] After fertilization, the concentration of hCG rapidly rises in both the urine and serum of pregnant women. The detection of hCG in these fluids is an excellent marker for confirming pregnancy. The Immuno*Card* STAT! hCG Combo Test is a rapid test which can detect the presence of hCG in urine or serum. The test utilizes monoclonal and polyclonal antibodies to hCG.

BIOLOGICAL PRINCIPLES

Immuno*Card* STAT! hCG Combo Test is a solid phase, sandwich-format immunochromatographic assay for the qualitative detection of hCG. Urine or serum is added to the sample well of the Test Device using the pipette provided. The sample migrates through reaction pads where hCG, if present in the sample, binds to a monoclonal anti-hCG dye conjugate. The sample then migrates across a membrane towards the results window, where the labeled hCG complex is captured at a test line region containing immobilized rabbit anti-hCG. Excess conjugate will flow past the test line region and be captured at a control line region containing an immobilized antibody directed against the anti-hCG dye conjugate (with or without hCG complexed to it).

The appearance of 2 black bands in the results window – one at "T: Test" and the other at "C: Control" – indicates the presence of hCG in the sample. If a detectable level of hCG is not present, only the control band will appear in the result window.

REAGENTS / MATERIALS PROVIDED

The maximum number of tests obtained from this test kit is listed on the outer box.

Immuno*Card* STAT! hCG Combo Test Devices individually pouched, each containing a disposable pipette.

- Membrane coated with rabbit polyclonal anti-alpha hCG
- Conjugate pad containing mouse monoclonal anti-beta hCG
- Directional Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or timer
- Sample collection cups or tubes
- Positive and Negative Controls

PRECAUTIONS

- All reagents are for in vitro diagnostic use only.
- Do not use beyond the expiration date printed on the kit or foil pouch.
- The lot numbers may be different on the foil pouch and the kit.
- Use appropriate precautions for the collection, handling, and storage of specimens. All human blood products should be treated as potentially infectious and handled with good laboratory practices using appropriate precautions recommended in the Centers for Disease Control / National Institutes of Health Manual, "Biosafety in Microbiological and Biomedical Laboratories."
- Dispose of all used Test Devices, pipettes and specimens in suitable biohazardous waste containers.
- Test Devices are stable in the unopened foil pouches until the expiration date. Do not remove the Test Device from the pouch until needed.

HAZARDS AND PRECAUTIONARY STATEMENTS

There are no known hazards associated with this product.

SHELF LIFE AND STORAGE

Store Immuno*Card* STAT! hCG Combo Tests at room temperature, 15 to 30 C (59 to 86 F), out of direct sunlight. Test Devices are stable until the expiration date printed on the kit or foil pouch. **DO NOT FREEZE.**

If the control band does not appear when running the test, the Test Cassette or kit may have been stored or handled improperly or the foil pouch may not have been intact.

PROCEDURAL NOTES

- If specimen has been stored refrigerated, allow it to warm to room temperature before use.
- Several tests can be run at the same time. Use a new pipette with each test to avoid contamination errors.

SPECIMEN COLLECTION AND PREPARATION

No filtration or centrifugation of urine or serum specimens is required for testing with the Immuno*Card* STAT! hCG Combo Test.

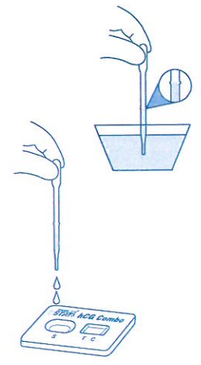
Urine
Urine specimens may be collected in any clean, dry, plastic or glass container. For early determination of pregnancy, the first morning specimen of urine is recommended since it usually contains the highest concentration of hCG. Urine specimens may be stored at room temperature 15 to 30 C (59 to 86 F) for up to 8 hours, or refrigerated at 2 to 8 C (35 to 46 F) for up to 72 hours.

Serum
Serum specimens should be obtained aseptically in tubes without anticoagulants. Plasma specimens are not suitable and should not be used for the Immuno*Card* STAT! hCG Combo Test. Serum specimens may be stored at 2 to 8 C (35 to 46 F) for up to 48 hours before testing. However, if testing is delayed beyond 48 hours, the serum specimens (separated from the clot) should be frozen at -20 C (-4 F) or colder. Frozen specimens may be stored for up to 1 year. The frozen specimens should be thawed, mixed, and brought to room temperature 15 to 30 C (59 to 86 F) before testing.

TEST PROCEDURE

Patient specimens and control material must be brought to room temperature (15-30 C; 59-86 F) prior to testing.

- Remove the Test Device and the pipette from the pouch. Place the Device on a flat surface.
- Squeeze the bulb of the pipette and insert the barrel into the patient sample. Release the bulb and draw up enough sample to **fill the barrel to the line indicated on the pipette. Do not overfill.**
- Expel the **entire** contents of the barrel (135 µL) into the sample well of the Test Device. No drop counting required.
- Discard the pipette in a suitable biohazardous waste container.
- Read results:
  3 minutes for urine
  5 minutes for serum
  Strong positive results may be observed sooner.
- **Results are invalid after the stated read time. The use of a timer is recommended.**



INTERPRETATION OF TEST RESULTS

Positive

Two separate black or gray bands – one at "T: Test" and the other at "C: Control" – are visible in the results window, indicating that the specimen contains detectable levels of hCG. While the intensity of the test band may vary with different specimens, the appearance of 2 distinct bands should be interpreted as a positive result.

Negative

If no band appears at "T" and a black or gray band is visible at the "C: Control" position the test can be considered negative, indicating that a detectable level of hCG is not present.

Invalid

If no band appears at the "C: Control" position, the test is invalid. The test is also invalid if incomplete or beaded bands appear at either "T: Test" or "C: Control." The test should be repeated using another Test Device.

Note: The test is valid if the control line appears by the stated read time regardless of whether the sample has migrated all the way to the end of the sample window.

QUALITY CONTROL

This test should be performed per applicable local, state, or federal regulations or accrediting agencies.

Internal Quality Control
Several procedural controls are incorporated into each Immuno*Card* STAT! hCG Combo Test for routine quality checks. It is recommended that these procedural controls be documented for each sample as part of daily quality control.

The same labeled conjugate antibody results in the appearance of both the test and the control bands. The appearance of the control band in the results window is an internal positive procedural control which validates the following:

Test System: The appearance of the control band assures that the detection component of both the test line and control line is intact, that adequate sample volume was added and that adequate capillary migration of the sample has occurred. It also verifies proper assembly of the Test Device.

Operator: The appearance of the control band indicates that an adequate volume of fluid was added to the sample well for capillary migration to occur. If the control band does not appear at the read time, the test is invalid. Appearance of the control band should be documented as part of the daily quality control.

The clearing of the background in the results area may be documented as a negative procedural control. It also serves as an additional capillary flow control. At the read time, the background should appear white to light gray and not interfere with the reading of the test. The test is invalid if the background fails to clear and obscures the observation of a distinct control band.
If the expected control reactions are not observed, repeat the control tests as the first step in determining the root cause of the failure. If control failures are repeated, please contact Meridian's Technical Services Department at 1-800-343-3858 (US) or your local distributor.

EXTERNAL QUALITY CONTROL

Meridian Bioscience recommends that external hCG controls be run with each new lot and with each new untrained operator.

EXPECTED VALUES

hCG is not normally detected in the urine and serum specimens of healthy men and non-pregnant women. In normal pregnancy, 20 mIU/mL hCG is reported to be present in both urine and serum 2 to 3 days before the first missed menstrual period.[18,19] The levels of hCG continue to increase up to 200,000 mIU/mL at the end of the first trimester.

Agreement

Urine
Urine specimens from 634 individuals were evaluated with the Immuno*Card* STAT! hCG Combo Test and the QuickVue®+ One-Step hCG-Combo Test. Samples were from patients seeking confirmation of pregnancy. The two assays were in agreement on 629 of the 634 samples. A radioimmunoassay (DPC Coat-A-Count© hCG IRMA Kit) was used to quantify the five discrepant results. Three of the discrepant samples were found to have an hCG concentration greater than 0 but less than 20 mIU/mL, the stated analytical sensitivity of both assays, and thus were removed from the analysis. One sample contained 0 mIU hCG/mL according to the IRMA and was scored negative by the Immuno*Card* STAT! test but positive by QuickVue+. The remaining sample contained >500 mIU hCG/mL according to the IRMA and was scored positive by the Immuno*Card* STAT! test but negative by QuickVue+.

Thus in this study, the Immuno*Card* STAT! hCG urine procedure had greater than 99% agreement with the comparative test methods in the 435 specimens testing negative and the 196 specimens testing positive.

		Comparative Methods (QuickVue+ Test and IRMA)	
		+	-
Immuno*Card* STAT! hCG Combo Test	+	196	0
	-	0	435

Agreement on Positive Samples: >99%
Agreement on Negative Samples: >99%
Total Agreement: >99%

Serum
Serum specimens from 691 individuals were evaluated with the Immuno*Card* STAT! hCG Combo Test and the QuickVue®+ One-Step hCG-Combo Test. Samples were from patients seeking confirmation of pregnancy. The two assays were in agreement on 679 of the 691 samples. A radioimmunoassay (DPC Coat-A-Count© hCG IRMA Kit) was used to quantify the twelve discrepant results. Eleven of the discrepant samples were found to have an hCG concentration greater than 0 but less than10 mIU/mL, the stated analytical sensitivity of both assays, and thus were removed from the analysis. The remaining sample contained 0 mIU hCG/mL according to the IRMA and was scored positive by the Immuno*Card* STAT! test but negative by QuickVue+.

Thus in this study, the Immuno*Card* STAT! hCG serum procedure had greater than 99% agreement with the comparative test methods.

Comparative Methods
(QuickVue+ Test and IRMA)

ImmunoCard STAT! hCG Combo Test	+	-
+	131	1
-	0	548

Agreement on Positive Samples: >99%
Agreement on Negative Samples: >99%
Total Agreement: >99%

Physician's Office Laboratory (POL) and Laboratory Study
A proficiency panel was prepared to allow for the evaluation of the urine and serum testing formats at three physician's offices and a clinical laboratory. A total of 80 samples were tested at each site. Purified hCG was spiked into horse serum as well as an artificial urine matrix. Each set (40 urine and 40 serum samples) contained negative, low positive, moderate positive and high positive samples. Each set was tested at each site over the course of three distinct runs. 100 % of the positive and negative results obtained by the POL operators on both urine and serum samples were in agreement with the expected values and with the results obtained by the clinical laboratory operators.

LIMITATIONS IN hCG TESTING

- This assay is capable of detecting only whole molecule (intact) hCG which is the predominant form of hCG in early pregnancy. It cannot detect the presence of hCG fragments or free subunits.
- In later term pregnancies (generally beyond the first trimester), occasional urine samples can contain very high levels of hCG fragments. Therefore, for urine testing, the ImmunoCard STAT! hCG Combo Test is most effective when used for the detection of pregnancy in its earlier stages.
- For diagnostic purposes, hCG test results should always be used in conjunction with other methods and in the context of the patient's clinical information (e.g., medical history, symptoms, results of other tests, clinical impression, etc.). Ectopic pregnancy cannot be distinguished from normal pregnancy by hCG measurements alone.[2,3]
- If the hCG level is inconsistent with, or unsupported by, clinical evidence, results should also be confirmed by an alternative hCG method. If a serum specimen is initially tested qualitatively, alternative methods may include the quantitative testing of serum or the qualitative testing of urine.[4] The absence of urinary hCG may suggest a falsely elevated serum result. Additionally, results may be confirmed by performing serial dilutions of the sample as usually, but not always, samples that contain interfering substances exhibit nonlinear results when diluted. **Test results should be confirmed using a quantitative hCG assay prior to the performance of any critical medical procedure.**
- Interfering substances may falsely depress or falsely elevate results. These interfering substances may cause false results over the entire range of the assay, not just at low levels, and may indicate the presence of hCG when there is none. As with any immunochemical reaction, unknown interferences from medications or endogenous substances may affect results.
- Infrequently, hCG levels may appear consistently elevated and could be due to, but not limited to, the presence of the following:[5-8]
  - heterophilic antibodies: Patients routinely exposed to animals or to animal serum products, can be prone to this interference and anomalous values may be observed
  - trophoblastic or nontrophoblastic neoplasms: abnormal physiological states that may falsely elevate hCG levels.[9,10] This test should not be used in the diagnosis of these conditions.
  - nonspecific protein binding
  - hCG like substances
- Specimens from patients who have received preparations of Mouse Monoclonal Antibodies for diagnosis or therapy may contain Human Anti-Mouse Antibodies (HAMA). Such specimens may demonstrate either falsely elevated or falsely depressed results when tested with assay kits which employ Mouse Monoclonal Antibodies.[11,12]
- Because of the high degree of sensitivity of the assay, specimens tested as positive during the initial days after conception may later be negative due to natural termination of the pregnancy. Overall, natural termination occurs in 22% of clinically unrecognized pregnancies and 31% of other pregnancies.[13] In the presence of weakly positive results, it is good laboratory practice to sample and test again after 48 hours.
- If the test band appears very faint, it is recommended that a new sample be collected 48 hours later and tested using another ImmunoCard STAT! hCG Combo Test Device.
- Dilute urine specimens may not have representative levels of hCG.
- Detection of very low levels of hCG does not necessarily indicate pregnancy[4] as low levels of hCG can occur in apparently healthy, nonpregnant subjects.[14,15] Additionally, post-menopausal specimens may elicit weak positive results due to low hCG levels unrelated to pregnancy. In a normal pregnancy, hCG values double approximately every 48 hours.[16] Patients with very low levels of hCG should be sampled and tested again after 48 hours, or tested with an alternative method.
- Some antipsychotic agents/drugs are known to cause false positive results in pregnancy tests.[17]

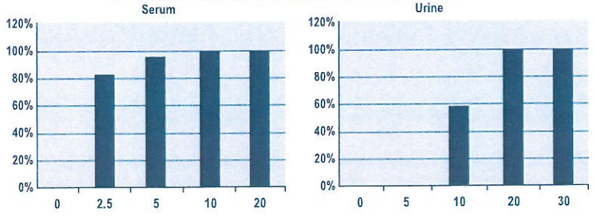
SPECIFIC PERFORMANCE CHARACTERISTICS

Analytical Sensitivity
The ImmunoCard STAT! hCG Combo Test will detect hCG in urine specimens with concentrations of 20 mIU/mL or more and in serum specimens with 10mIU/mL or more (calibrated against WHO 3rd IS 75/537). Specimens containing 1,000,000 mIU/mL (spiked with purified hCG) will also give positive results.

- The expected sensitivity of *urine* samples at a read time of 3 minutes is 20 mIU/mL
- The expected sensitivity of *serum* samples at a read time of 5 minutes is 10 mIU/mL

Note: Samples containing minute quantities of hCG (below 10 mIU/mL) may develop faint test bands.

% of samples containing varying amounts of hCG interpreted as positive



CROSSREACTIVITY
The addition of luteinizing hormone (300 mIU/mL of LH), follicle stimulating hormone (1000 mIU/mL of FSH), or thyroid stimulating hormone (1000 µIU/mL of TSH) to negative urine and serum specimens gives negative results in the ImmunoCard STAT! hCG Combo Test.

TESTS FOR INTERFERING SUBSTANCES
The following substances were added to urine and serum specimens containing 0 or 20 mIU/mL (urine) or 10 mIU/mL (serum) hCG. The substances at the concentrations listed below were not found to affect the performance of the test.

Urine

Acetaminophen	20 mg/dL	Gentisic acid	20 mg/dL
Acetoacetic acid	2000 mg/dL	Glucose	2000 mg/dL
Acetyl salicylic acid	20 mg/dL	Hemoglobin	250 mg/dL
Amitriptyline	100 mg/dL	Human albumin	2000 mg/dL
Amphetamines	10 ug/mL	Ibuprofen	40 mg/dL
Ascorbic acid	20 mg/dL	Imipramine	100 mg/dL
Atropine	20 mg/dL	Lithium	3.5 mg/dL
Benzoylecogonine	10 mg/dL	Mesoridazine	1mg/dL
Bilirubin	2 mg/dL	Methadone	10 mg/dL
Caffeine	20 mg/dL	Morphine	6 ug/mL
Cannabinol	10 mg/dL	Nortriptyline	100 mg/dL
Chlorpromazine	5 mg/dL	Phenobarbital	15 mg/dL
Codeine	10 mg/dL	Phenylpropanolamine	20 mg/dL
Desipramine	20 mg/dL	Pregnanediol	1500 ug/dL
Diazepam	2 mg/dL	Progesterone	40 mg/mL
Ephedrine	20 mg/dL	Proteins	2000 mg/dL
Estradiol	25 ng/mL	Salicylic acid	20 mg/dL
Estriol	1 mg/dL	Tetracycline	20 mg/dL
Hydroxybutyrate	2000 mg/dL	Thioridazine	2 mg/dL
Ethanol	200 mg/dL		

Serum

Amitriptyline	100 mg/dL	Lithium	3.5 mg/dL
Amphetamines	10 ug/mL	Mesoridazine	1 mg/dL
Benzoylecogonine	10 mg/dL	Methadone	10 mgldL
Bilirubin	30 mg/dL	Morphine	6 ug/mL
Cannabinol	10 mg/dL	Nortriptyline	100 mg/dL
Chlorpromazine	5 mg/dL	Phenobarbital	15 mg/dL
Codeine	10 mg/dL	Phenothiazine	2 mg/dL
Desipramine	20 mg/dL	Pregnanediol	1500 ug/dL
Diazepam	2 mg/dL	Progesterone	40 ng/mL
Estradiol	25 ng/mL	RF factor	40 IU/mL
Estriol	1 mg/dL	Tetracycline	20 mg/dL
Hemoglobin	500 mg/dL	Thioridazine	2 mg/dL
Ibuprofen	40 mg/dL	Triglycerides	2000 g/dL
Imipramine	100 mg/dL		

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REORDER

No. 755425 (25 tests)

TRADEMARK

MANUFACTURED FOR:

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Sekisui Diagnostics, LLC 6659 Top Gun Street, San Diego, CA 92121 USA Tel: 781.652.7800

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SYMBOL USAGE

YOU MAY SEE ONE OR MORE OF THESE SYMBOLS ON THE LABELING/PACKAGING OF THIS PRODUCT.

	Use By / Utilizzare entro / Utiliser jusque / Fecha de caducidad / Verwendbar bis	CONTROL +	Positive control / Controllo positivo / Contrôle positif / Control positivo / Positive Kontrolle
LOT	Batch Code / Codice del lotto / Code du lot / Código de lote / Chargenbezeichnung	CONTROL −	Negative control / Controllo negativo / Contrôle négatif / Control negativo / Negative Kontrolle
IVD	In vitro diagnostic medical device / Dispositivo medico-diagnostico in vitro / Dispositif médical de diagnostic in vitro / Dispositivo médico para diagnóstico in vitro / In-Vitro-Diagnostikum	EC REP	Authorized Representative in the European Community / Rappresentante Autorizzato nella Comunità Europea / Mandataire dans la Communauté européenne / Representante autorizado en la Comunidad Europea / Bevollmächtigter in der Europäischen Gemeinschaft
CE	This product fulfills the requirements of Directive 98/79/EC on in vitro diagnostic medical devices / Questo prodotto soddisfa i requisiti della Direttiva 98/79/CE sui dispositivi medico-diagnostici in vitro / Ce produit répond aux exigences de la Directive 98/79 CE relative aux dispositifs médicaux de diagnostic in vitro / Este producto cumple con las exigencias de la Directiva 98/79/CE sobre los productos sanitarios para diagnóstico in vitro / Dieses Produkt entspricht den Anforderungen der Richtlinie über In Vitro Diagnostica 98/79/EG.	SMP PREP DIL SPE	Sample Preparation Apparatus containing Sample Diluent / Dispositivo per la preparazione del campione contenente il diluente del campione / Système pour la préparation de l'échantillon, diluant inclus / Aparato para Preparación de Muestra con Diluyente de Muestra / System zur Probenvorbereitung, in dem sich Probenverdünnungspuffer befindet
REF	Catalogue number / Numero di catalogo / Référence du catalogue / Número de catálogo / Bestellnummer		Do not freeze / Non congelare / Ne pas congeler / No congelar / Nicht Einfrieren
	Consult Instructions for Use / Consultare le istruzioni per l'uso / Consulter les instructions d'utilisation / Consulte las instrucciones de uso / Gebrauchsanweisung beachten	BUF RXN	Reaction Buffer / Tampone di reazione / Solution de réaction tamponnée / Tampon de Reacción / Reaktionspuffer
	Manufacturer / Fabbricante / Fabricant / Fabricante / Hersteller		For IVD Performance Evaluation Only / Soltanto per valutazione delle prestazioni / Réactifs IVD réservés à l'évaluation des performances / Sólo para evaluación del funcionamiento / Nur zur IVD Leistungsbewertung
Σ	Contains sufficient for <n> tests / Contenuto sufficiente per "n" saggi / Contenu suffisant pour "n" tests / Contenido suficiente para <n> ensayos / Inhalt ausreichend für <n> Prüfungen	SOLN STOP	Stopping Solution / Soluzione di fitop / Solution d'arrêt / Solución de parada / Stopplösung
	Temperature limitation / Limiti di temperatura / Limites de température / Límite de temperatura / Temperaturbegrenzung	CONJ ENZ	Enzyme Conjugate / Coniugato enzimatico / Conjugué enzymatique / Conjugado enzimático / Enzymkonjugat
SN	Serial number / Numero di serie / Numéro de série / Número de serie / Seriennummer	CONTROL	Assay Control / Controllo del test / Test de contrôle / Control de Ensayo / Kontrolltest
TEST	Test Device / Dispositivo test / Dispositif de test / Dispositivo de Prueba / Testgerat	REAG	Reagent / Reagente / Réactifs / Reactivos / Reagenzien
	Date of manufacture / Data di fabbricazione / Date de fabrication / Fecha de fabricación / Herstellungsdatum	BUF WASH	Wash Buffer / Soluzione di lavaggio / Solution de lavage / Tampón de lavado / Waschpuffer
BUF	Buffer / Soluzione tamponé / Solution tamponnée / Tampón / Puffer		Warning / Avvertenza / Mise En Garde / Advertencia / Warnhinweise
CONJ	Conjugate / Coniugato / Conjugué / Conjugado / Konjugat	DIL SPE	Specimen Diluent (or Sample Diluent) / Diluente del Campione / Diluant échantillons / Diluyente de muestra / Probenverdünnungspuffer
SUBS	Substrate / Substrato / Substrat / Substrato / Substrat	BUF WASH 20X	Wash Buffer Concentration: 20X / Soluzione di lavaggio 20X / Solution de lavage concentrée 20X / Solución tampón de lavado 20X / 20fach konzentriertes Waschlösungsmittel
		DET REAG	Detection Reagent / Reagente Diretto / Réactif de Détection / Reactivo de Detección / Nachweis Reagenz

For technical assistance, call Technical Support Services at 800.343.3858 between the hours of 8AM and 6PM, USA Eastern Standard Time. To place an order, call Customer Service Department at 800.543.1980.