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PartoSure[®] Test Instructions for Use



Version 1



For In Vitro Diagnostic Use



0197



TTDT-1-20-IVDR



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Intended Use

The PartoSure[®] Test is a rapid, non-instrumented, qualitative immunochromatographic test for the in vitro detection of placental alpha microglobulin-1 (PAMG-1) in vaginal secretions of pregnant women using a sterile vaginal swab provided in the kit. The device is designed as an aid to rapidly assess the risk of preterm delivery in ≤ 7 days from the time of cervicovaginal sample collection in pregnant women with signs and symptoms of preterm labor, intact amniotic membranes, and minimal cervical dilatation (≤ 3 cm), sampled between 20 weeks, 0 days and 36 weeks, 6 days gestation.

Intended User

The PartoSure Test is intended for use in a clinical setting by trained healthcare professionals and is not intended for self-testing.

Description and Principle

Summary and explanation

An accurate risk assessment of preterm birth is clinically important among pregnancies with threatened preterm labor. This is particularly true with respect to both the administration of corticosteroids, which have an optimal benefit within 7 days of administration,¹ as well as the transfer of patients to a tertiary care center capable of caring for the birth of a premature infant. Clinical evaluation alone, including the measurement of cervical length and dilatation, is not sufficiently predictive of imminent delivery.² Similarly, currently available biomarker tests, such as those based on the detection of fetal fibronectin, have extremely poor predictive values for imminent delivery.³ Thus, the accurate prediction of time to delivery in patients with threatened preterm labor remains an important clinical concern. The high negative and positive predictive values of the PartoSure Test may allow for the timely identification of patients that would benefit from available interventions such as antenatal corticosteroids. Additionally, a more accurate identification of these patients may likely reduce the costs associated with unnecessary admissions caused by the poor positive predictive values of existing methods. The test kit is a self-contained system that provides rapid, qualitative results without outside instrumentation or an invasive speculum examination.

The PartoSure Test is a lateral flow, immunochromatographic assay designed to identify the presence of human placental alpha microglobulin-1 (PAMG-1) in amniotic fluid. PAMG-1 was selected as a marker for accurate risk assessment of preterm birth due to its unique characteristics, i.e., its high level in amniotic fluid, low level in blood, and extremely low background level (50–220 picograms/mL) in cervico-vaginal discharge, i.e., the “normal” population. The test employs monoclonal antibodies sufficiently sensitive to detect 1 ng/mL of PAMG-1 once eluted into the solvent vial, which is the cut-off concentration for a positive result of the “affected” population. With a dilution of 3-4-fold once eluted into the solvent vial, the cut-off concentration is 13–18 times above the maximum background PAMG-1 concentration.

For the analysis, a sample of cervicovaginal discharge collected by vaginal swab is extracted into a solvent. The presence of PAMG-1 antigen is then detected by inserting a lateral-flow test strip into the vial. The sample flows from an absorbent pad to a nitrocellulose membrane, passing through a reactive area containing monoclonal anti-PAMG-1 antibodies conjugated to a gold particle. The antigen-antibody complex flows to the test region where it is immobilized by a second anti-PAMG-1 antibody. This event leads to the appearance of the test line. Unbound antigen-antibody complexes continue to flow along the test strip and are immobilized by a second antibody. This leads to the appearance of the internal control line.

Materials Provided

Kit contents

Kit	(20)
Catalog no.	TTDT-1-20-IVDR
	Units/Kit
PartoSure Test Strip sprayed with murine anti-PAMG-1 monoclonal antibodies, goat anti-murine antibodies, and contains bovine serum albumin	20 strips
PartoSure Solvent	20 x 550 µL
Sterile Flocked Vaginal Swab	20 swabs
<i>PartoSure Test Instructions for Use</i>	1

Components of the kit

The principal components of the kit are explained below.

The PartoSure Test kit includes the following components: the PartoSure Test strip in a foil pouch with desiccant, a vial containing the PartoSure Solvent, and a sterile flocked vaginal swab. Ethylene Oxide is the sterilization method used for the flocked swab sterilization.

Controls

The PartoSure Test strip contains an internal procedural control mechanism that ensures analytical functionality. The appearance of one or two lines in the results region of the test strip verifies the integrity of the test procedure and components.

Materials Required but Not Provided

Additional reagents

No additional materials are required to perform the PartoSure Test.

Warnings and Precautions

Please be aware that you may be required to consult your local regulations for reporting serious incidents that have occurred in relation to the device to the manufacturer and/or its authorized representative and the regulatory authority in which the user and/or the patient is established.

For *in vitro* diagnostic use.

Safety information

When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate safety data sheets (SDSs). These are available online in convenient and compact PDF format at www.qiagen.com/safety where you can find, view, and print the SDS for each QIAGEN kit and kit component.

- Specimens and samples are potentially infectious and used PartoSure Test kits are biohazardous. Discard sample and assay waste according to your local safety procedures.
- Safety precautions should be observed when collecting test samples.
- PartoSure Test strips include substances of animal origin which might contain infectious viable transmissible agents, albeit with a very low probability. Appropriate precautions should be followed when handling test strips.
- These instructions for use must be followed exactly; failure to do so may lead to inaccurate results.
- The PartoSure Test result should not be interpreted as absolute evidence for the presence or absence of a process that will result in delivery ≤ 7 days from specimen collection.

- The PartoSure Test result should always be used in conjunction with information available from the clinical evaluation of the patient and other diagnostic procedures such as cervical examination, assessment of uterine activity, and evaluation of other risk factors.
- Results should be interpreted with caution when a specimen is obtained from a patient with unconfirmed gestational age.
- Specimens should be collected prior to collection of culture specimens. Collection of vaginal specimens for microbiologic culture frequently requires aggressive collection techniques that may abrade the cervical or vaginal mucosa and may potentially interfere with sample preparation.
- Specimens should not be obtained from patients with suspected or known placental abruption or placenta previa.
- Use of any test strip (e.g., AmniSure), swab or solvent solution other than the one provided with the test kit is prohibited.
- The PartoSure Test is for *in vitro* diagnostic use only and no component of the test kit, other than the swab, should come into contact with the patient.
- PartoSure Test performance has been characterized from specimens taken from the vaginal cavity. Samples obtained from other locations should not be used. A speculum examination is not required.
- PartoSure Test kit components are for single use only.
- PartoSure Test results are qualitative and not quantitative. No quantitative interpretation should be made based on the strength of the test or control lines.
- The intensity of the lines may vary; the test result is valid even if the lines are faint or uneven. Do not interpret the test result based on the intensity of the lines.

Emergency information

CHEMTREC

Outside USA & Canada +1 703-527-3887

Precautions

PartoSure Solvent

WARNING



Contains sodium azide. May be harmful if swallowed. Wear protective gloves/ protective clothing/ eye protection/ face protection. Sodium azide may react with plumbing to form potentially explosive metal azides. Avoid contact with skin, eyes, and clothing. In case of contact with any of these reagents, wash area thoroughly with water. If disposing of this reagent, always flush the drain with large volumes of water to prevent azide build-up.

Further information

- Do not use the PartoSure Test after the expiration date, which is printed on the product packaging.
- Do not use the kit if the swab or test strip package integrity is compromised or if the solvent vial has leaked.
- Do not bend or fold the test strip or the foil pouch with the test strip in it; doing so may damage the strip and lead to inaccurate results.

Reagent Storage and Handling

Attention should be paid to the expiration dates and storage conditions printed on the box and labels of all components. Do not use expired or incorrectly stored components.

In-use stability

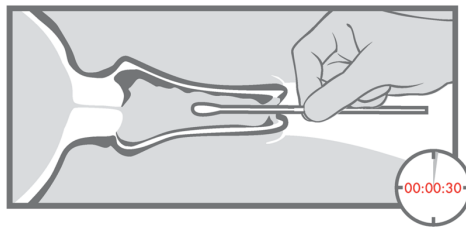
- Store the PartoSure Test kit in a dry place at 15–25°C (59–77°F). The test should not be frozen.
- When stored in the foil pouch at the recommended temperature, the test is stable until the expiration date printed on the pouch.
- The PartoSure Test strip should be used within six (6) hours after removing the test strip from the foil pouch.

Specimen Storage and Handling

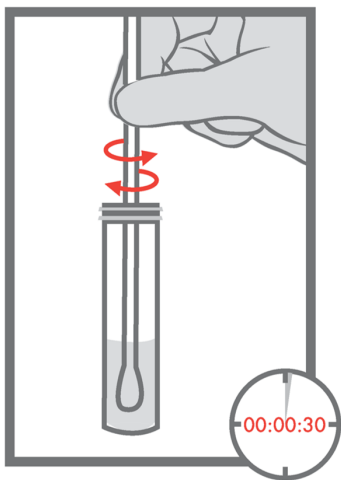
Treat all samples as potentially infectious. Discard sample and assay waste according to your local safety procedures.

Specimen collection

1. Take the solvent vial by its cap and ensure all liquid in the vial has dropped to the bottom. Open the solvent vial and place it in a vertical position.
2. To collect a sample from the vagina, use only the sterile flocked swab provided with the PartoSure Test kit. Remove the swab from its package and follow the instructions on the packaging. The tip of the swab should not touch anything prior to insertion into the vagina. Hold the swab by the middle of its shaft and, while the patient is lying on her back, carefully insert the tip of the swab into the vagina until the fingers contact the skin (no more than 5–7 cm deep). Withdraw the swab from the vagina after 30 seconds.



3. After the swab has been removed from the vagina, immediately place the tip into the provided solvent vial and rinse by rotating for 30 seconds.



4. Remove the swab from the vial and dispose of it.

Specimens not tested within 24 hours of collection must be stored refrigerated at 2–8°C and tested within five days of collection.

PartoSure Test Protocol

Important points before starting

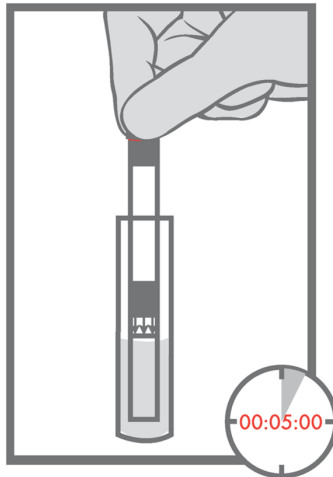
A result is only considered valid if a control line is seen; the images below depict result possibilities.

Setting up

Tear open the foil pouch at the tear slits and remove the PartoSure Test strip.

Procedure

1. Insert the white end of the test strip (marked with arrows facing downward) into the solvent vial.

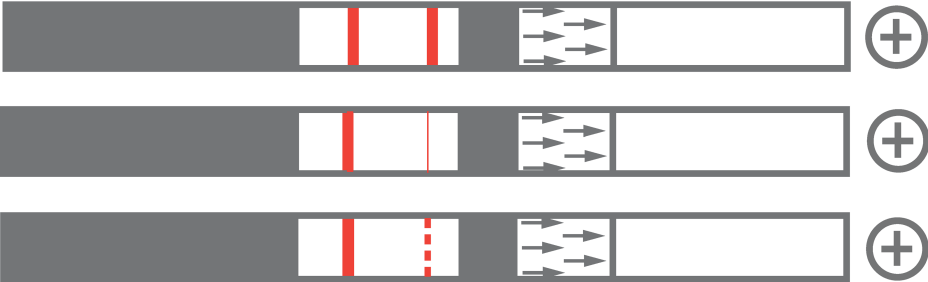


2. Remove the test strip from the vial if two lines are clearly visible on the strip's test area (white space between the two green 'blocks') or after 5 minutes sharp. Read the results by placing the test strip on a clean, dry, and flat surface in a well-lit environment via either natural or fluorescent lighting. A positive result is indicated by two lines in the test area, while a negative result is indicated by a single line in the control region. Do not read or interpret the results after 10 minutes have passed since inserting the test strip into the vial.

Interpretation of Results

Two lines: Positive

Control Line Test Line



One line: Negative

Control Line Test Line



No Control line: Invalid

Control Line Test Line



Positive: Two Lines

Imminent delivery within ≤ 7 days is highly likely

Negative: One Control Line

Imminent delivery within ≤ 7 days is highly unlikely

Invalid: No Lines or Test Line Only

Results not valid; retest

The intensity of the lines may vary; the test result is valid even if the lines are faint or uneven. Do not interpret the test result based on the intensity of the lines.

Limitations

- The PartoSure Test should only be used in patients with signs and symptoms of preterm labor.
- Take care not to contaminate the swab or cervicovaginal secretions with personal lubricants (e.g., K-Y[®] lubricating jelly). When the specimen contains > 25% of personal lubricant, it may interfere with absorption of the specimen by the swab or with the antibody-antigen reaction of the PartoSure Test and lead to invalid test results.
- If it is suspected that the patient has applied a topical disinfectant (e.g., Miconazole nitrate cream) to the vaginal area within 24 hours, delay specimen collection until 24 hours from application of the topical disinfectant have passed as these products, when greater than 32% of the specimen, can lead to false-negative test results.
- The PartoSure Test is not intended for use in women with moderate or gross vaginal bleeding. The presence of vaginal bleeding may contribute to difficulty in interpreting the PartoSure Test result. Testing a moderately to grossly bloody sample may lead to false-positive results. If upon visual examination you are concerned about the presence of moderate or gross vaginal blood, it is recommended that the sample be collected following the cessation of active vaginal bleeding.
- If concentrations of *Trichomonas vaginalis* greater than 10^5 cells/mL are present in a specimen, false-negative test results may occur.

Performance Characteristics

Analytical performance

Limit of Detection

The PartoSure Test cutoff of PAMG-1 at 1 ng/mL was confirmed by testing 30 replicates at 0.1 ng/mL increments of PAMG-1 ranging from 0.5 ng/mL to 1.0 ng/mL. Table 1 below provides the percentages of negative and positive calls for each concentration tested and their corresponding 95% confidence intervals.

Table 1. Percentage of negative and positive calls at each PAMG-1 concentration and corresponding 95% confidence interval.

PAMG-1 Concentration	PartoSure Test Results			Proportion of Positive Samples			
	Negative	Positive	Total	Fraction	%	Lower 95% Confidence Interval	Upper 95% Confidence Interval
0.5 ng/mL	28	2	30	2/30	6.67%	0.82%	22.07%
0.6 ng/mL	21	9	30	9/30	30.00%	14.73%	49.40%
0.7 ng/mL	7	23	30	23/30	76.67%	57.72%	90.07%
0.8 ng/mL	6	24	30	24/30	80.00%	61.43%	92.29%
0.9 ng/mL	4	26	30	26/30	86.67%	69.28%	96.24%
1.0 ng/mL	0	30	30	30/30	100.00%	88.43%	100.00%

The results of this study demonstrated 100% positive readings at the PartoSure Test cutoff concentration.

Although unlikely that a significant amount of amniotic fluid, and thus, PAMG-1 would be found in a vaginal specimen without a rupture of membrane, a study was conducted to ensure

no hook effect was possible with the PartoSure Test. In this investigation, 10 replicates of PAMG-1 at 40,000 times above the cutoff concentration (40 µg/mL) were tested by six separate lots. All 60 samples across all lots yielded a positive result, supporting a measuring range of 1–40,000 ng/mL.

Analytical specificity (cross-reactivity)

A study was conducted to determine the effects on the performance of the PartoSure Test by potential cross-reactive substances that may be found in vaginal specimens. These include proteins and hormones produced during pregnancy or found where PartoSure Test sampling occurs, including human Chorionic Gonadotropin, Trophoblastic beta-2 glycoprotein, Human placental lactogen, Alpha 1 Fetoprotein, IGFBP-3, and Human serum albumin. Cross-reactive substance concentrations in this study were based on published reference levels^{4,5,6,7,8}. Table 2 below provides the results from the cross-reactivity testing.

Table 2. Cross-reactive Substance Test Results

Substance	Highest Concentration Tested ⁸	Interference?
Human Chorionic Gonadotropin	111 mIU/mL	No
Trophoblastic beta-2 glycoprotein	0.75 µg/mL	No
Human placental lactogen	68.75 ng/mL	No
Alpha 1 fetoprotein	81.25 ng/mL	No
IGFBP-3	247.75 ng/mL	No
Human serum albumin	3.25 g/L	No

*Concentrations tested were in-vial after sample elution; clinical samples would contain ~4 times these concentrations.

Precision

A panel of PAMG-1 specimens at varying concentrations were evaluated for intra-assay precision. Three different operators interpreted five (5) replicates of each panel member using

three (3) different lots of the PartoSure Test for a total of 45 determinations per level. Table 3 below provides the percentages of negative and positive percent agreement categorized by each test sample's PAMG-1 concentration and test strip lot.

Table 3. Percentage of negative and positive agreement at each PAMG-1 concentration and test strip lot, with respective corresponding 95% confidence intervals

Agreement Measure	PAMG-1 Concentration	Lot	Frequency of Results in Agreement	% in Agreement	Lower Exact Two-sided 95% Confidence Limit	Upper Exact Two-sided 95% Confidence Limit
NPA	0.0 ng/mL	1	15/15	100.00%	78.20%	100.00%
NPA	0.0 ng/mL	2	15/15	100.00%	78.20%	100.00%
NPA	0.0 ng/mL	3	15/15	100.00%	78.20%	100.00%
NPA	0.2 ng/mL	1	15/15	100.00%	78.20%	100.00%
NPA	0.2 ng/mL	2	15/15	100.00%	78.20%	100.00%
NPA	0.2 ng/mL	3	15/15	100.00%	78.20%	100.00%
NPA	0.5 ng/mL	1	15/15	100.00%	78.20%	100.00%
NPA	0.5 ng/mL	2	15/15	100.00%	78.20%	100.00%
NPA	0.5 ng/mL	3	15/15	100.00%	78.20%	100.00%
PPA	1.0 ng/mL	1	15/15	100.00%	78.20%	100.00%
PPA	1.0 ng/mL	2	15/15	100.00%	78.20%	100.00%
PPA	1.0 ng/mL	3	15/15	100.00%	78.20%	100.00%
PPA	2.0 ng/mL	1	15/15	100.00%	78.20%	100.00%
PPA	2.0 ng/mL	2	15/15	100.00%	78.20%	100.00%
PPA	2.0 ng/mL	3	15/15	100.00%	78.20%	100.00%

Reproducibility

A multi-center reproducibility study was conducted to evaluate performance of the PartoSure Test across study sites with multiple operators. Three sites, representing intended testing locations of hospitals and health centers, were employed for the study, and each site used three different operators to conduct the testing. Test samples consisted of a five (5) member panel of varying PAMG-1 concentrations:

- Sample 1: Negative (No PAMG-1, sample is Solvent Solution)
- Sample 2: Low-Negative (0.2 ng/mL of PAMG-1)
- Sample 3: High-Negative (0.5 ng/mL of PAMG-1)
- Sample 4: Concentration at the analytical cut-off (1.0 ng/mL of PAMG-1)
- Sample 5: 2X concentration above the analytical cut-off (2.0 ng/mL of PAMG-1)

Five replicates of each concentration were tested by each operator at each site for a total of 15 replicates per site and 45 replicates for each concentration. Table 4 below provides the percentages of negative and positive percent agreement categorized by each test sample’s PAMG-1 concentration and test site.

Table 4. Percentage of negative and positive agreement at each PAMG-1 concentration and site, with respective corresponding 95% confidence intervals

Agreement Measure	PAMG-1 Concentration	Site	Frequency of Results in Agreement	% in Agreement	Lower Exact Two-sided 95% Confidence Limit	Upper Exact Two-sided 95% Confidence Limit
NPA	0.0 ng/ml	1	15/15	100.00%	78.20%	100.00%
NPA	0.0 ng/ml	2	15/15	100.00%	78.20%	100.00%
NPA	0.0 ng/ml	3	15/15	100.00%	78.20%	100.00%
NPA	0.2 ng/ml	1	15/15	100.00%	78.20%	100.00%
NPA	0.2 ng/ml	2	15/15	100.00%	78.20%	100.00%

Table 4. Percentage of negative and positive agreement at each PAMG-1 concentration and site, with respective corresponding 95% confidence intervals (continued)

Agreement Measure	PAMG-1 Concentration	Site	Frequency of Results in Agreement	% in Agreement	Lower Exact Two-sided 95% Confidence Limit	Upper Exact Two-sided 95% Confidence Limit
NPA	0.2 ng/ml	3	15/15	100.00%	78.20%	100.00%
NPA	0.5 ng/ml	1	15/15	100.00%	78.20%	100.00%
NPA	0.5 ng/ml	2	15/15	100.00%	78.20%	100.00%
NPA	0.5 ng/ml	3	15/15	100.00%	78.20%	100.00%
PPA	1.0 ng/ml	1	15/15	100.00%	78.20%	100.00%
PPA	1.0 ng/ml	2	15/15	100.00%	78.20%	100.00%
PPA	1.0 ng/ml	3	15/15	100.00%	78.20%	100.00%
PPA	2.0 ng/mL	1	15/15	100.00%	78.20%	100.00%
PPA	2.0 ng/mL	2	15/15	100.00%	78.20%	100.00%
PPA	2.0 ng/mL	3	15/15	100.00%	78.20%	100.00%

Interfering substances

A study was conducted to determine the effects on the performance of the PartoSure Test by potential interfering substances that may be found in vaginal specimens. The substances were classified as:

- Endogenous (17-OH-progesterone, Maternal blood, Maternal urine, and Semen)
- Antibiotics/Antifungals (Ampicillin, Cephalexin, Erythromycin, Gentamycin, and Miconazole Cream)
- Women's healthcare products (Betadine Feminine Wash, personal lubricant, surgical lubricant, and soap)

- Therapeutic drugs used for pregnancy complications (Dexamethasone, Magnesium sulphate, Oxytocin, Ritodrine, and Terbutaline)
- Micro-organisms (Group B *Streptococcus agalactiae*, *Trichomonas vaginalis*, *Candida albicans*, and *Gardnerella vaginalis*)

Interferant concentrations were based on reference levels^{9,10,11,12}, pathological values^{13,14}, and therapeutic ranges^{15,16}. If substances interfered, they were diluted further for follow-up testing. Table 5 below provides the results from the interference testing at the highest concentrations tested. Table 6 below provides results from the follow-up testing.

Table 5. Initial Interfering Substance Test Results

Substance or Micro-Organism	Concentrations Tested*	Interference?
17-OH-progesterone	62.5 µg/mL	No
**Trace Maternal Blood	10% v/v	No
**Moderate Maternal Blood	20% v/v	Yes
**"Gross" Maternal Blood	30% v/v	Yes
Maternal Urine	12.5% v/v	No
Semen	12.5% v/v	No
Ampicillin	18.8 µg/mL	No
Cephalexin	31.5 µg/mL	No
Erythromycin	34.5 µg/mL	No
Gentamycin	7.5 µg/mL	No
Miconazole Cream	12.5% w/v	Yes
Betadine Feminine Wash	5% v/v	No
Personal Lubricant	12.5% w/v	Yes
Surgical Lubricant	12.5%	No
Soap	1% w/v	Yes

Table 5. Initial Interfering Substance Test Results (continued)

Substance or Micro-Organism	Concentrations Tested*	Interference?
Dexamethasone	0.3 µg/mL	No
Magnesium Sulfate	50 µg/mL	No
Oxytocin	58 µU/mL	No
Ritodrine	100 µg/mL	No
Terbutaline	1 mg/mL	No
Group B <i>Streptococcus agalactiae</i>	1 x 10 ⁷ cfu/mL	No
<i>Trichomonas vaginalis</i>	1 x 10 ⁷ cells/mL	Yes
<i>Candida albicans</i>	1 x 10 ⁷ cells/mL	No
<i>Gardnerella vaginalis</i>	1 x 10 ⁷ cfu/mL	No

*Concentrations tested were in-vial after sample elution; clinical samples would contain ~4 times these concentrations.

** Blood admixtures classified by physicians as “moderate” or “gross” may yield false-positive results, whereas blood admixtures classified as “trace” do not interfere with the PartoSure Test.

Substances that showed interference in the initial testing were further diluted to where performance of the PartoSure Test was not affected. Table 6 lists the substances and the concentrations that did not interfere.

Table 6. Follow-up Interfering Substance Test Results

Substance or Micro-Organism	Non-interfering Concentrations*
Miconazole Cream	8% w/v
Personal Lubricant	6,25% w/v
Soap	0.5% w/v
<i>Trichomonas vaginalis</i>	4 x 10 ⁵ cells/mL

*Concentrations tested were in-vial after sample elution; clinical samples would contain ~4 times these concentrations.

Clinical performance

The clinical performance of the PartoSure Test was assessed in multiple peer-reviewed publications describing the use of the Test in clinical studies. To be included in the review, the papers had to list methods that included performing the PartoSure Test according to its Instructions for Use (IFU) available at the time, briefly summarized in their respective Materials and Methods section. Also, data were only analyzed for the preterm delivery in ≤ 7 days, as some publications included additional timeframes in their analyses.

A total of 17 publications¹⁷⁻³³ fit the criteria listed above, and they included 3186 women. From those data, sensitivities, specificities, their respective frequency percentages, and 95% Confidence Intervals were calculated. They are listed in Table 7.

Table 7. Sensitivity and Specificity Assessment for the PartoSure Test

Sensitivity			Specificity		
Frequency	%	95% CI	Frequency	%	95% CI
182/323	56.35%	(50.75%, 61.83%)	2743/2863	95.81%	(95.01%, 96.51%)

Additionally, Positive and Negative Predictive Values, their respective frequency percentages, and 95% Confidence Intervals were calculated. The summary of those data is listed in Table 8.

Table 8. Positive and Negative Predictive Value Assessment for the PartoSure Test

PPV			NPV		
Frequency	%	95% CI	Frequency	%	95% CI
182/302	60.26%	(54.50%, 65.82%)	2743/2884	95.11%	(94.26%, 95.87%)

Finally, positive and negative likelihood ratios were calculated, and those results are listed in Table 9.

Table 9. Positive and Negative Likelihood Ratios for the PartoSure Test

Positive Likelihood Ratio	Negative Likelihood Ratio
13.443	0.456

As a demonstration of the trueness of the PAMG-1 biochemical marker, the PartoSure Test was evaluated based on a systematic review and meta-analysis of three tests recommended by the European Association of Perinatal Medicine³⁴ (EAPM), regarding Preterm Labor and Birth Management. The PartoSure Test showed the highest combination of NPV and PPV in the context of three biochemical markers (fFN, PAMG-1 and pHGFBP-1) in cervical-vaginal secretions in symptomatic women with cervical lengths between 1.5 cm and 3.0 cm (the majority of patients presenting with symptoms of preterm delivery). Thus, the clinical data from Tables 7–9 combined with the recommendations of the EAPM, the Trueness of the PartoSure Test has been demonstrated.

Summary of Safety and Performance

The summary of safety and performance section can be downloaded from the PartoSure Test product webpage: resources.qiagen.com/TTDT-1-20-IVDR. This can also be found on the EUDAMED website.

Disposal

Observe relevant biological specimen handling guidelines. Dispose of samples and materials in accordance with local regulations.

When disposing of the PartoSure Solvent, always flush the drain with large volumes of water to prevent azide build-up.

References

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Symbols

The following symbols appear in the instructions for use or on the packaging and labeling:

Symbol

Symbol definition



Contains reagents sufficient for <N> reactions



Use by



This product fulfills the requirements of the European Regulation 2017/746 for in vitro diagnostic medical devices.



Authorized representative in the European Community / European Union



In vitro diagnostic medical device



Catalog number



Lot number



Material number (i.e., component labeling)



Component



Contains

Symbol

Symbol definition



Number



Global Trade Item Number



Unique Device Identifier

Rn

R is for revision of the Instructions for Use and n is the revision number



Temperature limitation



Manufacturer



Date of Manufacture



Consult instructions for use



Warning/caution



Do not reuse

Symbol

Symbol definition



Contains biological material of animal origin



Sterilized using ethylene oxide



Do not resterilize



Single sterile barrier system



Do not use if package is damaged



Not for self-testing



Near-patient testing

Each pack contains:

Each pack contains:

The PartoSure Test is a rapid, non-instrumented, qualitative immunochromatographic test for the in vitro detection of placental alpha microglobulin-1 (PAMG-1) in vaginal secretions of pregnant women using a sterile vaginal swab and is not intended for self-testing.

The PartoSure Test is a rapid, non-instrumented, qualitative immunochromatographic test for the in vitro detection of placental alpha microglobulin-1 (PAMG-1) in vaginal secretions of pregnant women using a sterile vaginal swab and is not intended for self-testing.

Warning: Do not fold or bend the foil pouch and/or the test strip.

Warning: Do not fold or bend the foil pouch and/or the test strip

Control Line

Control Line

Symbol

Symbol definition

Test Line

Test Line

Ordering Information

Product	Contents	Cat. no.
PartoSure Test (20)	20 Test Strips, Sterile Flocked Swabs, and Solvent Vials	TTDT-1-20-IVDR

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Document Revision History

Revision

Description

R1, November 2024

Initial release (commercial)

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