



Field Safety Notice (FSN) Letter

Date Issued

August 19, 2026

Product

Product Description	Part Number (PN)	Ordering Number	Lot Number (LN)/Serial Number (SN)	UDI	Impacted Labeling Versions Through
InstAlert™ hCG One Step Pregnancy Test Strip (Urine)	FHC-101	4564649001	All lots currently in your inventory within the expiration date	00810124272579	40002633 2023-02-27
Surestep™ hCG One Step Pregnancy Test Device (Urine)	FHC-102	4564719002	All lots currently in your inventory within the expiration date	00810124272647	40001851 2023-02-23
InstAlert™ hCG One Step Pregnancy Test Device (Urine)	FHC-102	4564679001	All lots currently in your inventory within the expiration date	00810124272609	40002635 2023-02-27

Purpose

The purpose of this letter is to communicate important product information and a field safety notice for the rapid human chorionic gonadotropin (hCG) tests listed above.

As part of routine post-market surveillance activities, an investigation was conducted into reports of false-positive results, and determined that while the tests demonstrate expected results at and above the established sensitivity levels, they may detect low levels of hCG below the stated assay sensitivity. This may result in false positive test results in samples from non-pregnant individuals.

As part of investigation performed, one false positive result was observed in a sample with reported concentration as low as 3.939 mIU/mL for serum, no false positives were observed for urine specimens tested with concentrations ranging through 3.469 mIU/mL.

These products are rapid one step tests intended to provide a presumptive diagnosis of pregnancy and for in-vitro professional use only. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated. Low levels of hCG may occur in certain populations, including individuals from the onset of peri-menopause, which may contribute to false positive results.

Impact on Patient's Results

False Positive (FP) result may occur when a visible line appears in the test region despite the patient not being pregnant which may lead to emotional distress, potential delay in appropriate care and unnecessary exploratory procedures guided by the initial false positive result.

This test is an aid in the detection of early pregnancy and results should be interpreted in conjunction with clinical and laboratory findings. Factors other than pregnancy including certain medical conditions as well as the naturally occurring physiological state of peri-menopause may result in low levels of hCG and a visible test line. If results are interpreted without consideration of these limitations, this may lead to misinterpretation of the test result.

Action by the Company:

This Field Safety Notice is being issued to clarify that the assay may detect low levels of hCG below the stated sensitivity in certain non-pregnant individuals. The existing limitation on the Instructions for Use (IFU) will be updated to include natural occurrence of low level hCG from the onset of peri-menopause, as a possible contributor to false positive results.

Until the IFU is updated, all future product lots will include a kit-insert reflecting these updates and clarifications. **A copy of the kit insert is also provided as an attachment to this notification.** Abbott is continuing the investigation of this issue. Should further information become available as a result of ongoing investigations, appropriate communication will be provided to customers as warranted.

Product Information**INTENDED USE**

The hCG test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine or serum (serum/urine combo tests only) to aid in the early detection of pregnancy.

LIMITATIONS

- A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG.^{6,7} **In addition, low levels of hCG can naturally occur from the onset of peri-menopause.^{8,9}**
- This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

REFERENCES

6. Dawood MY, BB Saxena, R Landesman "Human chorionic gonadotropin and its subunits in hydatidiform mole and choriocarcinoma", Obstet. Gynecol. 1977; 50(2): 172-181
 7. Braunstein GD, JL Vaitukaitis, PP Carbone, GT Ross "Ectopic production of human chorionic gonadotropin by neoplasms", Ann. Intern Med. 1973; 78(1): 39-45
 8. Jennifer A Sneyd, T Shannon Haymond, J Curtis A Parvin, AM Gronowski, and David G Grenache. "Diagnostic considerations in the measurement of human chorionic gonadotropin in aging women." Clinical Chemistry 51, No.10, 2005; 1830-1835
 9. Abugrave, NM. "Background hCG in non-pregnant individuals: Need for more sensitive point-of-care and over-the-counter pregnancy tests." L.A. Cole, D.G. Ladner / Clinical Biochemistry 42 (2009); 168-175
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Actions to be taken by the Customer/User:

Please take the following actions to minimize the risk of misinterpretation:

- In situations where an unexpected test result is obtained, consider all limitations, including peri-menopause that may result in low levels of hCG. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated, and an alternate confirmatory test that supports a timely clinical decision has been considered.
 - Acknowledge receipt of this letter. Your organization's reply provides Abbott with the necessary documentation to monitor the effectiveness of the field action notification.
 - If you have forwarded the product listed in the "Product" section to other laboratories within your distribution network, notify them of this Field Safety Notice and provide them with a copy of this letter.
 - Please retain this letter for your records.
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This FSN has been reported to the relevant Competent Authorities.

Contact Information

If you or any of the healthcare providers you serve have questions regarding this information, please contact Technical Service using the appropriate contact details below.

If you have experienced any patient or user injury associated with this notification, please immediately report the event to your local Technical Service.

Technical Service Contact Details:

Europe (General): +44 161 483 9032

Netherlands: 0800 022 5823

Ireland: +44 161 483 5884

Italy: +39 02 2774131

Spain: +34 936 008 008

Portugal: +44 161 483 9032

Email:

Europe, Netherlands, Ireland, Portugal: EME.TechSupport@abbott.com

Italy: EME.TechSupportIT@abbott.com

Spain: EME.TechSupportES@abbott.com



Kit Insert

IMPORTANT PRODUCT INFORMATION

Dear Valued Customer,

This notice is being provided to communicate that an investigation was conducted into false-positive reports for Abbott hCG rapid tests and identified that while the tests demonstrate expected results at and above the established sensitivity levels, they may detect low levels of hCG below the stated assay sensitivity, which may result in a visible test line in samples from non-pregnant individuals.

As part of the investigation performed, one false positive result was observed in a sample with reported concentration as low as 3.939 mIU/mL for serum, no false positives were observed for urine specimens tested with concentrations ranging through 3.469 mIU/mL.

The current limitation is being updated to clarify that, in addition to the previously described conditions, **low levels of hCG can occur naturally from the onset of peri-menopause**. Therefore, the presence of hCG in urine or serum specimens should not be used to diagnose pregnancy unless these conditions have been ruled out. This update will be incorporated in a future revision of the Instructions for Use (IFU).

As a reaffirmation, this test provides a **presumptive** diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

There is no change to the test procedure when used according to the Instructions for Use. Abbott is continuing the investigation of this issue. Should further information become available as a result of ongoing investigations, appropriate communication will be provided to customers as warranted.

Please retain this notice with the product and ensure all testing and/or laboratory personnel are aware of this information. If you or any healthcare providers you serve have questions regarding this information, please contact your local Abbott Technical Service.

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Rev. AA 2026/08

Field Safety Notice – Acknowledgement form

ENTER PRODUCT DESCRIPTION AND PART NUMBER YOU ARE ACKNOWLEDGING RECEIPT FOR:

Product Description	Part Number (PN)

Account / Customer Number
Healthcare Organization Name*
Distributor Name, if applicable
Street*
City*
State*
Zip Code, Country*
Contact Name*
Department/Unit
Title or function
Telephone number*
E-mail*

[illegible]

***Mandatory fields**

1. We acknowledge receipt of the Field Safety Notice Letter.
2. We confirm that all areas where the product could be located have been checked.
3. **SELECT ALL STATEMENTS THAT APPLY**

The following has been verified:

☐ We do not have any affected product(s).

☐ Affected product was redistributed to another facility. The contact information for that facility is:

☐ We have affected product(s). We acknowledge that low levels of hCG may be detected in certain non-pregnant individuals, potentially resulting in a visible test line and false-positive interpretation, including in populations at the onset of peri-menopause. We also acknowledge that this test provides a presumptive diagnosis of pregnancy and requires confirmation based on clinical and laboratory findings.

Signature and Date

Please complete and return this form within **10 business days** of receipt.