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Date March 1st, 2022

Document Ref# IMC22-04

Urgent Field Safety Notice:

IMMULITE® 2000
IMMULITE® 2000 XPi

Human Chorionic Gonadotropin (HCG) Potential Carryover from High Samples

Dear Sirs,

Our records indicate that your facility may have received the following product(s):

Table 1. IMMULITE 2000/IMMULITE 2000 XPi Affected Product(s)

Assay/Test Code	Siemens Material Number (SMN)	Catalog Number	Unique Device Identification (UDI)	Lot Number
HCG	10381206	L2KCG2	00630414961132	All lots
HCG	10381194	L2KCG6	00630414961149	All lots

Reason for Correction

The purpose of this communication is to inform you of an issue with the product(s) indicated in Table 1 above and provide instructions on actions that your laboratory must take.

Siemens Healthcare Diagnostics Inc. has confirmed the potential for falsely elevated hCG results due to sample carryover. This can be observed when a sample is assayed for hCG immediately after an undiluted sample with a hCG value of >5000 mIU/mL. This issue impacts serum and urine patient samples, as well as quality control samples and adjustors. The effect of carryover varies based on the concentration of the high hCG sample. See Table 2 in “Additional Information” section below.

There is currently no indication that the IMMULITE/IMMULITE 1000 HCG and Turbo HCG assays are impacted.

Siemens Healthcare Diagnostics understands the urgency of this situation and is actively investigating the root cause.

Risk to Health

The potential for clinical impact due to sample carryover is extremely unlikely. When this issue occurs, the potential exists for reporting erroneously elevated hCG levels which could lead to the misinterpretation of a viable pregnancy or result in an alternate course of therapy. Clinical impact is mitigated by correlation to clinical presentation and symptomology, imaging, as well as serial measurements of hCG. Siemens is not recommending a review of previously generated results.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Perform the instructions provided in Additional Information.
- Complete and return the Field Action Effectiveness Check Form attached to this letter within 7 days.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Healthineers technical support representative.

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your local Siemens Healthineers technical support representative.

Sincerely yours,

Siemens Healthcare Diagnostics GmbH

Signature: *Electronically signed by: Roland Ertl Reason: I am approving this document Date: Feb 28, 2022 17:14 GMT+1*

Email: roland.re.ertl@siemens-healthineers.com

i.A. Roland Ertl, MA
Quality Management CEE

Signature: *Electronically signed by: Carina Marie Viehboeck Reason: I have reviewed this document Date: Feb 28, 2022 17:39 GMT+1*

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i.A. DI Carina Viehböck
Product Manager Austria & SEE

Additional Information

Based on the amount of carryover observed and the potential clinical impact the following instructions are being provided:

1. If the HCG result on a sample is between 2.5 mIU/mL and 750 mIU/mL, repeat the sample. For instructions on setting up the system to automate this process, refer to the IMMULITE 2000 Systems Operators Guide (Rev 2), “Configuring Reflexive Tests”, section 8-15 (see Appendix 1 below for screenshots).
    a. If the values of the duplicate results are not within expected precision of the assay, run a further repeat on the sample.
2. If the HCG result on a sample is <2.5 mIU/mL or >750 mIU/mL, no actions are required, and the results can be reported.
3. As indicated in the Instructions for Use the results obtained from this assay should always be used in combination with the clinical examination, patient medical history, and other findings.

Table 2: Observed Carryover from an Undiluted High HCG Sample to a Low HCG Sample

Expected HCG result (mIU/mL)	Observed HCG result (mIU/mL)	Concentration of sample causing carryover (mIU/mL) *
<1.00	12.82	108653
1.42	7.00	88735
2.12	10.57	88581
2.52	15.23	116910
2.55	8.67	92937
3.36	13.25	95144
6.50	10.73	118527
7.13	14.55	117695

*Carryover was assessed with undiluted samples.

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Appendix 1:

Configuring Reflexive Tests

Follow the instructions in this section to specify tests to run automatically if a result is either below, within, or above a specified range.

Note Reflexive testing cannot be performed on a manually diluted sample.

Activating Reflexive Testing

To activate reflexive testing, perform the following steps:

1. At the Menu screen, select **Configure**.
2. Select **Configuration Settings**.
3. In the Testing Options box, select the **Reflexive Testing** option.
4. Select **Save**.

Setting up Reflexive Testing

To set up reflexive testing for assays or allergens, perform the following steps:

1. Select **MENU**.
2. At the MENU screen, select **Reflexive Tests**.
3. In the Principle Test Selection box, select a Principle Test Selection option. This selection determines what tests display in the Principle Test field.

Principle Test Selection	Description
Immunoassay – All Available	All assays scanned into system
Immunoassay – Configured for Reflex	Assays configured for reflexive testing
Allergy – All Available	All allergens and universal reagents scanned into the system
Allergy – Configured for Reflex	Allergens/universal reagent combinations configured for reflexive testing

4. Select a **Principle Test**, and if applicable, select a **Universal Reagent**.
5. From the following, select a new range type:
   - Only one **Below** range and one Above range can be configured per assay, or allergen and universal reagent combination.

     The **Below** and **Above** ranges cannot overlap.
   - Unlimited **Within** ranges can be configured if the values do not overlap with the Below and Above ranges.
   - For a qualitative assay, the New Range options are **Non Reactive**, **Indeterminate**, and **Reactive**.

     Only one of each may be added.
6. Select **Add Range**.

   Note For qualitative assays, the Reflex Range field is not available and displays Non Reactive. Proceed to step 8.
7. Enter the **Reflex Range** values based on the type of range that was selected in step 5.
8. In the TEST CATEGORIES box, select **IMMUNOASSAY** or **ALLERGY**.

   If **ALLERGY** is selected, select the appropriate universal reagents.
9. Select the buttons that correspond to the individual reflexive tests for this range (up to 15 tests per reflexive range).

   If necessary, use the Next Page and Previous Page buttons to locate additional tests.

   Note The Do Not Autosend option will be enabled if a reflexive test matching the principle test is selected. Select the Do Not Autosend option to prevent the results of the principle test and the matching reflexive test from being sent to the LIS. For example, if HCG reflexes to HCG and TSH and Do Not Autosend is selected, only the TSH result will be sent to the LIS.
10. To add a dilution for a reflexive test:
    a. Select a test under the Tests Selected heading.
    b. Select **DILUTION**.

       The Dilution Factor window displays.
    c. Select the dilution factor.
11. Select **Save** after selecting all of the necessary reflexive tests.
12. Repeat steps 5 through 11 to configure additional ranges for a principle test, or steps 2 through 11 to order reflex tests for a different assay or allergen.
13. To print the contents of the Current Ranges box, select **Print**.
14. Select **Close** to close the Reflexive Testing Configuration screen.