

**IMMULITE<sup>®</sup> 2000**  
**IMMULITE<sup>®</sup> 2000 XPi**  
**VersaCell<sup>™</sup>**

### Level Sensing Associated with Dropped Sample Tubes

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Our records indicate that your facility may have an IMMULITE<sup>®</sup> 2000/IMMULITE<sup>®</sup> 2000 XPi analyzer connected to the VersaCell<sup>™</sup> system.

#### Reason for Correction

Siemens Healthcare Diagnostics is conducting a correction for the IMMULITE 2000/IMMULITE 2000 XPi analyzer connected to a VersaCell system. This configuration (IMMULITE 2000 connected to the VersaCell system) has been available since May 2003.

Siemens has determined through investigation of a small number of customer complaints that there is a potential for incorrect results to be reported from processing of a sample tube if all of the following conditions occur on the IMMULITE 2000/IMMULITE 2000 XPi analyzer connected to a VersaCell system:

- a. The VersaCell system drops a sample tube during transfer to the IMMULITE 2000/IMMULITE 2000 XPi automation rack. The use of non-approved tubes, caps on tubes, and incorrectly placed barcode labels increase the likelihood of dropped tubes.
- b. The IMMULITE 2000/IMMULITE 2000 XPi system proceeds with level sensing in the empty position, leading to aspiration of air instead of sample.
- c. The VersaCell system error message, "**Error 2019**: The robot arm is jammed. Please remove the tube from the gripper," is not addressed.
- d. The IMMULITE LIS configuration for holding results allows the result to be transmitted to the LIS by the VersaCell system.
- e. The result is not verified at the VersaCell and/or LIS prior to being reported.

This issue can only occur with VersaCell systems that are connected to IMMULITE 2000/IMMULITE 2000 XPi systems. This issue does not affect any other analyzer that interfaces with the VersaCell system.

Not every instance of a dropped tube will lead to incorrect results. Refer to the "Additional Information" sections for specific scenario information.

## Risk to Health

This issue may lead to the misreporting of a patient sample as a discrepant low result or less than the lower limit of the assay. Look back is not required as any critical result would be addressed immediately. There are no reports of injury or illness due to this issue.

## Actions to be Taken by the Customer

- Rerun any dropped sample tube associated with a VersaCell Error 2019 and processed on the IMMULITE 2000/IMMULITE 2000 XPi analyzer prior to reporting patient results. Refer to the “Verify Results from the Dropped Tube” section for more information.
- Verify all dropped sample tube results at the VersaCell and/or LIS prior to reporting results.
- Please review this letter with your Medical Director.
- Perform the instructions provided in Additional Information (A) to correct the issue if it has occurred and/or Additional Information (B) to prevent this issue from occurring.

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 has caused. Siemens is investigating this issue and will inform customers when a solution is available. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

## Additional Information (A)

If a dropped tube occurs on your laboratory’s IMMULITE 2000/IMMULITE 2000 XPi analyzer connected to the VersaCell system, an error message will always display on the VersaCell screen. Perform the following based on the error displayed, then verify the results from the dropped tube:

**Error 2019:** The robot arm is jammed. Please remove the tube from the gripper.

**Explanation:** The VersaCell system robotic arm encountered an error when placing a tube in the drawer. The VersaCell system automatically stops. In addition to the error, a tube status of **Transfer Error** displays for the sample tube that was processed at the time of the error. Often, the robotic arm will present the tube in the gripper to the operator. However, there are instances when a tube is not present in the gripper. This may be an indicator that a tube was dropped.

When the VersaCell system displays a message to remove a sample tube from the gripper, as instructed in the VersaCell Operator’s Guide, perform the following:

1. Select **Unlock Door**.
2. Lift the main door.
3. Hold the sample tube and gripper, angle them toward you and remove the tube. If there is no tube in the gripper, gently pull the gripper toward you. You hear the sound of air being released.

**Note: Please refer to the below instructions if there is no tube in the gripper.**

4. Resolve the error.
5. Close the main door.
6. Select **Lock Door**.
7. Select **Run**.

**Error 2019 with no tube in gripper:** The robot arm is jammed. Please remove the tube from the gripper.

**Explanation:** If this error displays but there is no tube in the gripper, verify the location of the tube.

Before selecting **Run** on the VersaCell system, perform the following:

1. Check the VersaCell Drawer screen for samples with a tube status of **Transfer Error**.
2. Select the tube position on the screen with the Transfer Error. This will display the sample accession number and any related result information, if available.
3. Visually check the physical drawer position for the presence of the sample tube that corresponds with the Transfer Error status. If the tube is in the VersaCell drawer position, the VersaCell gripper returned the tube successfully.
4. Select **Run** and continue processing.

If the tube is not present in the physical drawer position that corresponds to the Transfer Error on the VersaCell Drawer screen, perform the following:

1. Perform a visual inspection of the VersaCell drawer area and inside the VersaCell cavity.
2. If the tube is not found in the VersaCell system, place the IMMULITE 2000/IMMULITE 2000 XPi system in **All Pause** mode, then open the IMMULITE 2000/IMMULITE 2000 XPi main cover.
3. Perform a visual inspection of the IMMULITE 2000/IMMULITE 2000 XPi sample carousel and surrounding areas.

If the tube is not found during initial inspection of either system, the tube may have dropped in an area of the analyzer that is not easily visible or accessible. Closer inspection of both systems may be necessary to locate the tube.

### **Verify Results from the Dropped Tube**

To verify results from the dropped tube, perform the following:

1. Search for the sample accession number on the VersaCell LIS screen to determine if patient results were received from the IMMULITE 2000/IMMULITE 2000 XPi.
2. Review the patient results, if available, and follow your laboratory procedures for rerunning samples.

3. Follow your laboratory procedures for handling and cleaning possible sample spillage using protective equipment, if necessary.

**Note:** It is recommended that test orders for the dropped sample tube for the IMMULITE 2000/IMMULITE 2000 XPi system be rerun.

### Additional Information (B)

The use of non-approved tubes, tubes with caps, and incorrectly placed barcode labels may result in a dropped tube event. To minimize the possibility of a dropped tube incident:

- Use uncapped tubes
- Use only supported tube types
- Ensure properly placed barcode labels

### Sample Tubes Supported

- Sizes: 12 x 75 mm to 16 x 100 mm
- Types: primary (gel separator), secondary (round bottom), glass and plastic, flat bottom

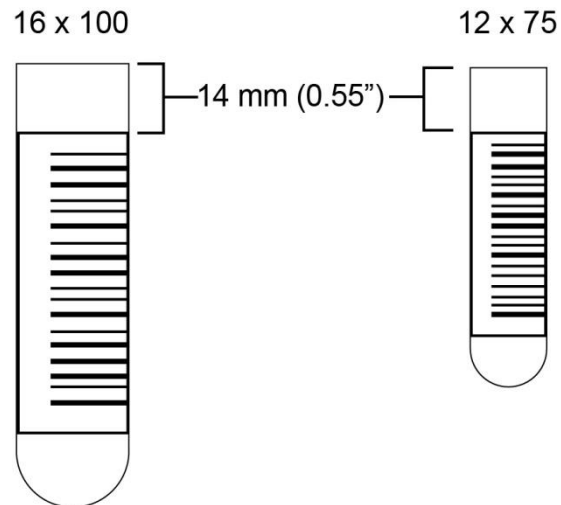
**Note:** Flat bottom sample tubes are only supported on VersaCell software version 3.6a or later and the SDX-07 rack must be used.

- The VersaCell can process sample tubes from many different vendors. Some sample tube types are known to generate errors or cause hazards and are considered to be at risk. Examples of these tubes and the potential hazards/errors are shown below:
  - Sample tubes with a lip around the edge
  - Screw top sample tubes of a size other than 16 mm cause the gripper to pick up the tube in a non-vertical orientation.
  - Sample tubes with protruding edges.
  - Tubes with tube top sample cups or smaller sample tubes inside larger tubes.
  - False-bottom sample tubes.
  - Sample tubes made of pliable plastic materials.

### Placement of Barcode Labels

Careful placement of the barcode labels on the sample tubes is critical. In addition to ensuring proper reading of the barcode, proper placement aids in avoiding possible dropped tubes. Sticky residue from barcode label glue or uneven labels from multiple labels on a single tube may cause the tube to stick to the arm gripper fingers.

Place each label with the barcode portion as high as possible on the sample tube, while leaving approximately 0.5" of tube for the gripper to grasp the tube. Refer to the diagram below.



The following specifications are referenced in the VersaCell Operator's Guide (10792978 Rev. A 2011-11):

- Place the barcode label at least 14 mm (0.55 inches) from the top of the sample tube and at least 20 mm (0.79 inches) from the bottom of the sample tube.
- Ensure that the barcode label is at least 10 mm (0.4 inches) high.

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