

**Atellica® IM 1300 Analyzer**  
**Atellica® IM 1600 Analyzer**

### **Ancillary Reagent Pack Overflow at Altitudes Greater than 350 Meters (1148 Feet)**

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Our records indicate that your facility may have received the following product and your facility is located at an altitude above 350 Meters (m) or 1148 Feet (ft).

**Table 1. Atellica IM Products**

<b>Product</b>	<b>Siemens Material Number (SMN)</b>
Atellica IM 1300 Analyzer	11066001
Atellica IM 1600 Analyzer	11066000

### **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 that Ancillary reagent packs used on Atellica IM 1300 and Atellica IM 1600 analyzers may overflow when pierced while on an analyzer located at an altitude of greater than 350 (m) or 1148 (ft) above sea level.

At altitudes greater than 350 (m) or 1148 (ft), the relative air pressure inside the Ancillary pack is increased due to the lower air pressure which may force the reagent up the aspiration port and out through the punctured seal creating a leak inside the Atellica analyzer chamber during initial aspiration.

The analyzers do not recognize the leak which creates a difference between the expected volume of the Ancillary pack and the actual volume remaining. As a result, customers at altitudes greater than 350 (m) or 1148 (ft) may observe an increased number of Reagent Volume Check Errors.

The difference of actual versus expected volume in the Ancillary pack volume has the potential to cause erroneously elevated results for complexed Prostate-specific antigen (cPSA) and erroneously depressed results for Total Thyroxine (T4) if insufficient or no ancillary reagent is dispensed. Ten patient samples were tested for cPSA and T4 and the difference in results generated with and without ancillary reagent is calculated in Table 2. For cPSA, an absolute difference of up to 1.96 ng/mL was observed for a sample with a result of 9.84 ng/mL and for T4,

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an absolute difference of up to (-) 2.9 ug/dL (37.3 nmol/L) was observed for a sample with a result of 8.9 ug/dL (114.5 nmol/L).

**Table 2. Atellica IM cPSA and T4 Difference in Results between Full Ancillary Packs and Empty Ancillary Packs**

cPSA				T4						
Results in ng/mL (ug/L)				Results in ug/dL				Results in nmol/L		
Sample	Full Ancillary Pack	Empty Ancillary Pack	Absolute Difference ( Empty-Full)	Sample	Full Ancillary Pack	Empty Ancillary Pack	Absolute Difference ( Empty-Full)	Full Ancillary Pack	Empty Ancillary Pack	Absolute Difference ( Empty-Full)
Sample 1	2.26	2.84	0.58	Sample 1	5.6	4.4	-1.2	72.2	57.1	-15.1
Sample 8	2.59	3.35	0.76	Sample 5	5.2	3.8	-1.4	66.5	48.9	-17.6
Sample 6	3.87	4.62	0.74	Sample 7	5.6	4.3	-1.3	72.0	54.9	-17.1
Sample 3	3.88	4.41	0.53	Sample 2	5.9	4.6	-1.3	75.9	59.3	-16.6
Sample 2	3.88	4.40	0.51	Sample 6	7.0	5.3	-1.6	89.8	68.5	-21.3
Sample 7	3.93	4.43	0.50	Sample 8	7.2	5.3	-1.9	92.5	68.6	-23.9
Sample 9	4.53	5.34	0.81	Sample 10	7.3	5.1	-2.2	94.6	66.0	-28.6
Sample 10	5.60	5.94	0.34	Sample 3	7.4	6.3	-1.1	95.8	81.8	-14.0
Sample 4	9.84	11.80	1.96	Sample 4	8.6	6.2	-2.4	110.4	79.7	-30.7
Sample 5	10.52	11.01	0.49	Sample 9	8.9	6.0	-2.9	114.5	77.2	-37.3

Siemens has determined that the packs do not leak when the fill port is punctured and resealed prior to the aspirate port seal being punctured. This action relieves pressure within the pack so that it will not leak on the instrument. As a mitigation, Siemens is providing instructions for puncturing the fill port and placing a seal over the puncture hole in the Additional Information section of this communication. Siemens will provide free of charge seals to reseal the Ancillary packs prior to placing the Ancillary packs on the system. The seals will be provided in kits of 60 and may be ordered using SMN 11208742 through normal ordering channels.

A modification of the ancillary pack is under evaluation.

### Risk to Health

When this issue occurs, there is a potential for a reduction in the number of available cPSA and total T4 ancillary tests due to ancillary pack leaking, leading to undetected reagent volume errors. The erroneously elevated cPSA results have a negligible clinical impact. The erroneously depressed total T4 results could lead to additional investigation for hypothyroidism which may include repeat and follow-up testing. Mitigations would include correlation of test results with patient's clinical history as well as with other diagnostic laboratory tests such as TSH and fT4, repeat testing and/or serial testing. Siemens Healthineers is not recommending a review of previously generated results due to the low probability of the issue.

### Actions to be Taken by the Customer

- Please review this letter with your Medical Director.

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- Perform the instructions provided in Additional Information.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 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 Customer Care Center or 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.

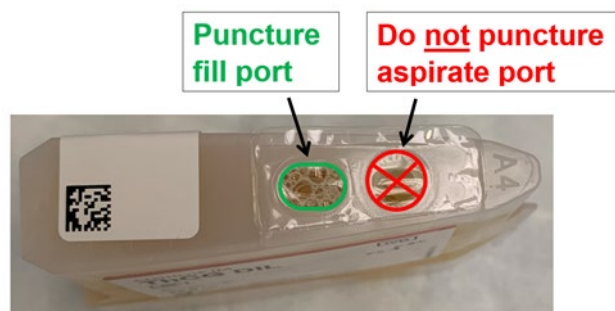
We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

### **Additional Information – Work around for laboratories at altitudes greater than 350(m) or 1148(ft)**

If your laboratory is at an altitude greater than 350(m) or 1148 (ft)

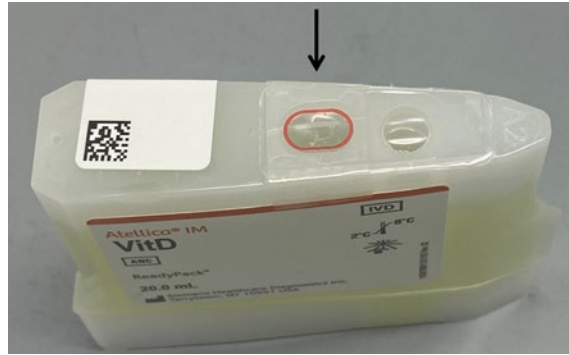
Before placing all filled Ancillary packs onboard the Atellica IM analyzer:

1. Ensure you are wearing appropriate PPE (Personal Protective Equipment), including protective glasses and gloves.
2. Place the Ancillary reagent pack on a flat surface.
3. Obtain a disposable sample tip and puncture the **fill port** as shown in the following image. Do not puncture the aspiration port.



4. Place a replacement seal 11208742 over the puncture hole as shown in the following image.

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- Ensure that all QC results are within the laboratory acceptable range before releasing or reporting patient results.

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**FIELD CORRECTION EFFECTIVENESS CHECK**

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This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice AIMC 21-07.A.OUS dated September, 2021 regarding Ancillary Reagent Pack Overflow at Altitudes Greater than 350 Meters (1148 Feet). Please read each question and indicate the appropriate answer.

Return this completed form to Siemens Healthcare Diagnostics as per the instructions provided at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice instructions provided Yes ☐ No ☐  
in this letter.

Name of person completing questionnaire: \_\_\_\_\_

Title: \_\_\_\_\_

Institution: \_\_\_\_\_

Instrument Serial Number: \_\_\_\_\_

Street: \_\_\_\_\_

City: \_\_\_\_\_

State: \_\_\_\_\_

Phone: \_\_\_\_\_

Country: \_\_\_\_\_

Please send a scanned copy of the completed form via email to XXXXX.

Or to fax this completed form to the Customer Care Center at: XXXXXX,

If you have any questions, contact your local Siemens Healthineers technical support representative.