URGENT

Ortho Clinical Diagnostics

October 2018

URGENT PRODUCT CORRECTION NOTIFICATION

Incorrect Determination of On-Analyser Stability Time on VITROS® XT 7600 Integrated Systems

Dear Customer,

Cc. Chairman Medical Board and relevant Heads of Department

This notification is to inform you of a software anomaly. Under specific conditions, the VITROS® XT 7600 Integrated System may incorrectly extend the on-analyser stability time for a loaded VITROS Reagent*.

VITROS System	Affected Software	Product Code	Unique Device Identifier No.
VITROS® XT 7600 Integrated Chemistry System	Version 3.4	6844461	1075870031658

*VITROS Reagents are defined as individual MicroWell packs, MicroSlide cartridges and/or Diluent packs, all MicroTip packs, including MicroTip Partnership Assays (MPAs) and User Defined Assays (UDAs)

Background Information

When VITROS Reagents are loaded, the VITROS XT 7600 System is designed to automatically determine:

- If a reagent pack or cartridge is full or partially used.
- If the Shelf Expiration Date for the reagent is included on the ADD loaded on your system.
- The on-analyser stability time, which is the amount of time the reagent may remain on the analyser to ensure optimal reagent performance.

Description of Anomaly and Impact to Results

Our investigation confirmed that under a specific scenario, a software anomaly will occur causing the VITROS XT 7600 System to incorrectly determine the reagent's on-analyser stability time. The identified scenario is outlined in the Question and Answer Section on Page 3.

When the anomaly occurs, the system could use reagents past their on-analyser stability time without alerting the user with a condition code or flagging the associated results with an RE (Reagent Expired) code.

In the event reagents are used beyond their specific on-analyser stability times, the associated test results may be affected.

Rate of Occurrence

Based on condition code data obtained via e-Connectivity®, approximately 96% of all cartridges/packs are emptied *before* their expected on-analyser expiration time, therefore the results would not be affected by this anomaly. The specific scenario related to the VITROS XT 7600 System involves loading a used cartridge with only one slide left, without specifying the date opened. The actual rate of this scenario cannot be determined through e-Connectivity, but is considered improbable.

Ortho has received no customer complaints related to this anomaly on VITROS XT 7600 Systems.

Detection

Any occurrence of this anomaly is not easily identifiable. However, performing daily quality control testing will help to assess if reagents are performing within expectations.

Resolution

The resolution to this anomaly will be included in the next version of software that is expected to be released in December 2018. In the interim, to prevent occurrence of the anomaly, please follow the instructions below.

REQUIRED ACTIONS

To prevent the occurrence of this anomaly until the new software version is installed:

- Newly opened reagents should be loaded normally using the Load/Unload process.
- To load partially used reagents, *or* full reagents that have been previously loaded on another system, do not use the Load/Unload process button. You must use Manual Load process following the V-docs Manual Load instructions for your system. Ensure that all information on the Manually Load Cart dialogue screen is complete and accurate for each cartridge loaded.

ADDITIONAL REQUIRED ACTIONS

- Complete and return the Confirmation of Receipt form no later than **November 1, 2018**.
- Post this notification by each VITROS 7600 System in your facility or with your user documentation.
- Please forward this notification if the product was distributed outside of your facility.

Contact Information

In the event reagents are used beyond their specific on-analyser stability times (OAS), the associated test results may be affected. The potential impact to test results that may be observed is obtainable from Ortho Care Technical Solutions Centre.

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre at 1800 5646766.

Questions and Answers

1. **What is "on-analyser stability time"?**

   VITROS Reagents all have a specific "on analyser stability time," which is the amount of time the reagent may remain on the analyser to ensure optimal reagent performance. This varies by reagent and is different from the shelf expiration date.

2. **How is the analyser supposed to work with regard to on-analyser stability time?**

   The analyser is intended to keep track of on-analyser stability time regardless of whether a reagent is full or partially used and loaded using the Load/Unload or Manual Load process.

3. **What scenario can cause the anomaly to occur?**

   Ortho has discovered the scenario below where the open expiration of a reagent may be incorrectly set. The scenario that can cause the anomaly is listed below.

   IMPORTANT to NOTE: The instructions provided under Required Actions will prevent your system from using reagents incorrectly beyond the on-analyser stability time indicated in the Instructions for Use.

Scenario that can cause the anomaly

The open expiration date for a partially used reagent loaded without specifying the date opened will be incorrectly assigned as if the reagent was full and will be given full on-analyser stability time. This occurs when a MicroSlide cartridge containing a single slide is loaded without specifying the date opened.

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Ortho Clinical Diagnostics

October 2018

URGENT PRODUCT CORRECTION NOTIFICATION

Incorrect Determination of On-Analyser Stability Time on VITROS® 5,1 FS Chemistry Systems

Dear Customer,

Cc. Chairman Medical Board and relevant Heads of Department

This notification is to inform you of a software anomaly. Under specific conditions, the VITROS® 5,1 FS Chemistry System may incorrectly extend the on-analyser stability time for a loaded VITROS Reagent*.

VITROS System	Affected Software	Product Code	Unique Device Identifier No.
VITROS® 5,1 FS Chemistry System	Version 3.0 & below	6801375	10758750001132

*VITROS Reagents are defined as individual MicroSlide cartridges, MicroTip packs, MicroTip Partnership Assays (MPAs) and User Defined Assays (UDAs), and/or Diluent packs.

Background Information

When VITROS Reagents are loaded, the VITROS 5,1 FS System is designed to automatically determine:

- If a reagent pack or cartridge is full or partially used.
- If the Shelf Expiration Date for the reagent is included on the ADD loaded on your system.
- The on-analyser stability time, which is the amount of time the reagent may remain on the analyser to ensure optimal reagent performance.

Description of Anomaly and Impact to Results

Our investigation confirmed that under specific scenarios, a software anomaly will occur causing the VITROS 5,1 FS System to incorrectly determine the reagent's on-analyser stability time. The identified scenarios are outlined in the Question and Answer Section on Page 4.

When the anomaly occurs, the system could use reagents past their on-analyser stability time without alerting the user with a condition code or flagging the associated results with an RE (Reagent Expired) code.

In the event reagents are used beyond their specific on-analyser stability times, the associated test results may be affected.

Rate of Occurrence

Based on condition code data obtained via e-Connectivity®, approximately 97% of all cartridges/packs are emptied *before* their expected on-analyser expiration time, therefore the results would not be affected by this anomaly.

The estimated frequency of occurrence of a VITROS Reagent being used after its expected on-analyser stability time due to this anomaly is approximately 1 in 1.5 million cartridges/packs.

Ortho has received no customer complaints related to this anomaly on VITROS 5,1 FS Systems.

Detection

Any occurrence of this anomaly is not easily identifiable. However, performing daily quality control testing will help to assess if reagents are performing within expectations.

Resolution

The resolution to this anomaly is included in Software Version 3.1 (MOD B9).

This product correction notification is being issued together with a communication about Software Version 3.1 (Ref. CL2018-112ea) and Release Notes for the new software that resolves the anomaly.

We anticipate that the software will be released via download during the week of October 29, 2018. Software Kits will be issued following the download release. Until MOD B9 is loaded on your VITROS 5,1 FS System, to prevent occurrence of the anomaly, please follow the instructions below.

REQUIRED ACTIONS

Reset System and Evaluate current reagent status (need to do one time only):

1. To reset your VITROS 5,1 FS System, after ensuring testing is complete, perform a Normal Shutdown and start-up of your system.
2. Based on your typical usage, assess which, if any, reagents currently loaded on your system are at risk of exceeding on-analyser stability time prior to being emptied (e.g., low-volume assays or assays with short on-analyser stability time, such as VITROS CRP). **NOTE:** Your usage may be such that all reagents are used prior to exceeding on-analyser stability time and that no packs/cartridges are "at risk."
3. Record the test count of each “at risk” reagent on the system (if any), and then remove the "at risk" reagents from your system. **Note:** MicroTip diluents do not display a test count.
4. Request credit for unused tests by using the Confirmation of Receipt form.

To prevent the occurrence of this anomaly until the new software version is installed:

For All Reagent Types:

- Ensure that the most recent ADD (i.e., latest DRV#) is installed prior to loading new lots of all reagents.
- Newly opened reagents should be loaded normally using the Load/Unload process. It is not necessary to perform any additional Shutdowns for reagents loaded using the Load/Unload process.
- To load partially used reagents, *or* full reagents that have been previously loaded on another system, first ensure all testing is complete. Do not use the Load/Unload process button. You must use Manual Load process following the V-docs Manual Load instructions for your system and the additional instructions below.

Manually Loading MicroSlide Cartridges:

1. In Reagent Management, use the Manual Load process. Ensure that all information on the Manually Load Cart dialogue screen is complete and accurate for each cartridge loaded.
2. Touch the Status button on the Reagent Management screen.
3. *When the reagent inventory process has been completed*, return to the System Status screen and immediately perform a Normal Shutdown, and then start-up your VITROS 5,1 FS System.

Manually Loading Reagent Packs (MicroTip, Diluents):

IMPORTANT NOTE: To load partially used packs, packs used on another VITROS System, and packs that have been removed from the same system for any reason (including to remove "Bubbles"), always use the Manual Load Process, specifying the barcode, shelf expiration and open date when prompted to do so.

On the Reagent Management screen, use the Manual Load process. Ensure that all information on the Manually Load Pack dialogue is complete and accurate for each pack loaded.

- If any full or partial pack has been previously loaded on the same analyser, the shelf expiration and open dates will automatically be populated once the barcode has been entered. It is **not necessary** to shut down and restart your system.
- If any full or partial pack has not been previously loaded on the same analyser, you must complete the open date on the Manually Load Pack dialogue, return to the System Status screen and immediately perform a Normal Shutdown, and then start-up your VITROS 5,1 FS System.

ADDITIONAL REQUIRED ACTIONS

- Complete and return the Confirmation of Receipt form no later than **November 1, 2018**.
- Post this notification by each VITROS 5,1 FS System in your facility or with your user documentation.
- Please forward this notification if the product was distributed outside of your facility.

Contact Information

In the event reagents are used beyond their specific on-analyser stability times (OAS), the associated test results may be affected. The potential impact to test results that may be observed is obtainable from the Ortho Care Technical Solutions Centre.

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre at *1800 5646766*.

Questions and Answers

1. **What is "on-analyser stability time"?**

   VITROS Reagents all have a specific "on-analyser stability time," which is the amount of time the reagent may remain on the analyser to ensure optimal reagent performance.

2. **How is the analyser supposed to work with regard to on-analyser stability time?**

   The analyser is intended to keep track of on-analyser stability time regardless of whether a reagent is full or partially used and loaded using the Load/Unload or Manual Load process.

3. **What scenarios can cause the anomaly to occur?**

   Ortho has discovered several scenarios where the open expiration of a reagent may be incorrectly set.

   The scenarios that may cause this issue are dependent on numerous factors, such as the actual supply slot the reagent was loaded into, or whether the slot had contained a previous reagent that had the open date manually entered. The scenarios that can cause the anomaly are listed below.

   IMPORTANT to NOTE: The instructions provided under Required Actions will prevent your system from using reagents incorrectly beyond the on-analyser stability time indicated in the Instructions for Use.

Scenario One

If the shelf expiration date for a reagent lot is not supported by the currently loaded ADD, the open expiration date for a partially used reagent of the unsupported lot will be incorrectly assigned as if the reagent was full.

Scenario Two

The expiration date for a partially used MicroSlide cartridge will be incorrectly reset to the expiration date of a new cartridge if:

- The slide supply containing the cartridge is re-initialized, ***and***
- After the cartridge is re-inventoried, the slide count is different by more than +-3 slides compared to the previous count, ***and***
- The same slot previously contained a cartridge that had been manually loaded with the open date manually entered, ***and***
- A shutdown and restart of the system had not been performed since the previous manual load event.

Scenario Three

The open expiration date for a partially used MicroSlide cartridge loaded without specifying the date opened will be incorrectly assigned as if the reagent was full and given full on-analyser stability time. This occurs when a cartridge containing a single slide is loaded without specifying the date opened.

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Ortho Clinical Diagnostics

October 2018

URGENT PRODUCT CORRECTION NOTIFICATION

Incorrect Determination of On-Analyser Stability Time on VITROS® 4600 Chemistry Systems

Dear Customer,

Cc. Chairman Medical Board and relevant Heads of Department

This notification is to inform you of a software anomaly. Under specific conditions, the VITROS® 4600 Chemistry System may incorrectly extend the on-analyser stability time for a loaded VITROS Reagent*.

VITROS System	Affected Software	Product Code	Unique Device Identifier No.
VITROS® 4600 Chemistry System	Version 3.3.1 & below	6802445	10758750012343

*VITROS Reagents are defined as individual MicroSlide cartridges, MicroTip packs, MicroTip Partnership Assays (MPAs) and User Defined Assays (UDAs), and/or Diluent packs.

Background Information

When VITROS Reagents are loaded, the VITROS 4600 System is designed to automatically determine:

- If a reagent pack or cartridge is full or partially used.
- If the Shelf Expiration Date for the reagent is included on the ADD loaded on your system.
- The on-analyser stability time, which is the amount of time the reagent may remain on the analyser to ensure optimal reagent performance.

Description of Anomaly and Impact to Results

Our investigation confirmed that under specific scenarios, a software anomaly will occur causing the VITROS 4600 System to incorrectly determine the reagent's on-analyser stability time. The identified scenarios are outlined in the Question and Answer Section on Page 4.

When the anomaly occurs, the system could use reagents past their on-analyser stability time without alerting the user with a condition code or flagging the associated results with an RE (Reagent Expired) code.

In the event reagents are used beyond their specific on-analyser stability times, the associated test results may be affected.

Rate of Occurrence

Based on condition code data obtained via e-Connectivity®, approximately 91% of all cartridges/packs are emptied *before* their expected on-analyser expiration time, therefore the results would not be affected by this anomaly.

The estimated frequency of occurrence of a VITROS Reagent being used after its expected on-analyser stability time due to this anomaly is approximately 1 in 1.82 million cartridges/packs.

Ortho has received no customer complaints related to this anomaly on VITROS 4600 Systems.

Detection

Any occurrence of this anomaly is not easily identifiable. However, performing daily quality control testing will help to assess if reagents are performing within expectations.

Resolution

The resolution to this anomaly will be included in the next version of software that is expected to be released in December 2018.

In the interim, to prevent occurrence of the anomaly, please follow the instructions below.

REQUIRED ACTIONS

Reset System and Evaluate current reagent status (need to do one time only):

1. To reset your VITROS 4600 System, after ensuring testing is complete, perform a Normal Shutdown and start-up of your system.
2. Based on your typical usage, assess which, if any, reagents currently loaded on your system are at risk of exceeding on-analyser stability time prior to being emptied (e.g., low-volume assays or assays with short on-analyser stability time, such as VITROS CRP). **NOTE:** Your usage may be such that all reagents are used prior to exceeding on-analyser stability time and that no packs/cartridges are "at risk."
3. Record the test count of each “at risk” reagent on the system (if any), and then remove the "at risk" reagents from your system. **Note:** MicroTip diluents do not display a test count.
4. Request credit for unused tests by using the Confirmation of Receipt form.

To prevent the occurrence of this anomaly until the new software version is installed:

For All Reagent Types:

- Ensure that the most recent ADD (i.e., latest DRV#) is installed prior to loading new lots of all reagents by using only the “All Assay Data” load option.
- Newly opened reagents should be loaded normally using the Load/Unload process. It is not necessary to perform any additional Shutdowns for reagents loaded using the Load/Unload process.
- To load partially used reagents, *or* full reagents that have been previously loaded on another system, first ensure all testing is complete. Do not use the Load/Unload process button. You must use Manual Load process following the V-docs Manual Load instructions for your system and the additional instructions below.

Manually Loading MicroSlide Cartridges:

1. In Reagent Management, use the Manual Load process. Ensure that all information on the Manually Load Cart dialogue screen is complete and accurate for each cartridge loaded.
2. Touch the Status button on Reagent Management screen.
3. *When the reagent inventory process has been completed,* return to the System Status screen and immediately perform a Normal Shutdown, and then start-up your VITROS 4600 System.

Manually Loading Reagent Packs (MicroTip, Diluents):

IMPORTANT NOTE: To load partially used packs, packs used on another VITROS System, and packs that have been removed from the same system for any reason (including to remove "Bubbles"), always use the Manual Load Process, specifying the barcode, shelf expiration and open date when prompted to do so.

On the Reagent Management screen, use the Manual Load process. Ensure that all information on the Manually Load Pack dialog is complete and accurate for each pack loaded.

- If any full or partial pack has been previously loaded on the same analyser, the shelf expiration and open dates will automatically be populated once the barcode has been entered. It is **not necessary** to shut down and restart your system.
- If any full or partial pack has ***not*** been previously loaded on the same analyser, you must complete the open date on the Manually Load Pack dialogue, return to the System Status screen and immediately perform a Normal Shutdown, and then start-up your VITROS 4600 System.

ADDITIONAL REQUIRED ACTIONS

- Complete and return the Confirmation of Receipt form no later than **November 1, 2018**.
- Post this notification by each VITROS 4600 System in your facility or with your user documentation.
- Please forward this notification if the product was distributed outside of your facility.

Contact Information

In the event reagents are used beyond their specific on-analyser stability times (OAS), the associated test results may be affected. The potential impact to test results that may be observed is obtainable from Ortho Care Technical Solutions Centre.

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre at 1800 5646766.

Questions and Answers

1. **What is "on-analyser stability time"?**

   VITROS Reagents all have a specific "on analyser stability time," which is the amount of time the reagent may remain on the analyzer to ensure optimal reagent performance.

2. **How is the analyser supposed to work with regard to on-analyser stability time?**

   The analyser is intended to keep track of on-analyser stability time regardless of whether a reagent is full or partially used and loaded using the Load/Unload or Manual Load process.

3. **What scenarios can cause the anomaly to occur?**

   Ortho has discovered several scenarios where the open expiration of a reagent may be incorrectly set.

   The scenarios that may cause this issue are dependent on numerous factors, such as the actual supply slot the reagent was loaded into and whether the slot had contained a previous reagent that had the open date manually entered. The scenarios that can cause the anomaly are listed below.

   IMPORTANT to NOTE: The instructions provided under Required Actions will prevent your system from using reagents incorrectly beyond the on-analyser stability time indicated in the Instructions for Use.

Scenario One
If the shelf expiration date for a reagent lot is not supported by the currently loaded ADD, the open expiration date for a partially used reagent of the unsupported lot will be incorrectly assigned as if the reagent was full.

Scenario Two
The expiration date for a partially used MicroSlide cartridge will be incorrectly reset to the expiration date of a new cartridge if:

- The slide supply containing the cartridge is re-initialized, ***and***
- After the cartridge is re-inventoried, the slide count is different by more than +/-3 slides compared to the previous count, ***and***
- The same slot previously contained a cartridge that had been manually loaded with the open date manually entered, ***and***
- A shutdown and restart of the system had not been performed since the previous manual load event.

Scenario Three
The open expiration date for a partially used MicroSlide cartridge loaded without specifying the date opened will be incorrectly assigned as if the reagent was full and given full on-analyser stability time. This occurs when a cartridge containing a single slide is loaded without specifying the date opened.

URGENT

Ortho Clinical Diagnostics

October 2018

URGENT PRODUCT CORRECTION NOTIFICATION

Incorrect Determination of On-Analyser Stability Time on VITROS® 5600 Integrated Systems

Dear Customer,

Cc. Chairman Medical Board and relevant Heads of Department

This notification is to inform you of a software anomaly. Under specific conditions, the VITROS® 5600 Integrated System may incorrectly extend the on-analyser stability time for a loaded VITROS Reagent*.

VITROS System	Affected Software	Product Code	Unique Device Identifier No.
VITROS® 5600 Integrated System	Version 3.3.1 & below	6802413 6802915	10758750002740 10758750007110

*VITROS Reagents are defined as individual MicroWell packs, MicroSlide cartridges, MicroTip packs, MicroTip Partnership Assays (MPAs) and User Defined Assays (UDAs), and/or Diluent packs.

Background Information

When VITROS Reagents are loaded, the VITROS 5600 System is designed to automatically determine:

- If a reagent pack or cartridge is full or partially used.
- If the Shelf Expiration Date for the reagent is included on the ADD loaded on your system.
- The on-analyser stability time, which is the amount of time the reagent may remain on the analyser to ensure optimal reagent performance.

Description of Anomaly and Impact to Results

Our investigation confirmed that under specific scenarios, a software anomaly will occur causing the VITROS 5600 System to incorrectly determine the reagent's on-analyser stability time. The identified scenarios are outlined in the Question and Answer Section on Page 4.

When the anomaly occurs, the system could use reagents past their on-analyser stability time without alerting the user with a condition code or flagging the associated results with an RE (Reagent Expired) code.

In the event reagents are used beyond their specific on-analyser stability times, the associated test results may be affected.

Rate of Occurrence

Based on condition code data obtained via e-Connectivity®, approximately 96% of all cartridges/packs are emptied *before* their expected on-analyser expiration time, therefore the results would not be affected by this anomaly.

The estimated frequency of occurrence of a VITROS Reagent being used after its expected on-analyser stability time due to this anomaly is approximately 1 in 3.3 million cartridges/packs.

Ortho has confirmed that one customer complaint to date was related to this anomaly.

Detection

Any occurrence of this anomaly is not easily identifiable. However, performing daily quality control testing will help to assess if reagents are performing within expectations.

Resolution

The resolution to this anomaly will be included in the next version of software that is expected to be released in December 2018.

In the interim, to prevent occurrence of the anomaly, please follow the instructions below.

REQUIRED ACTIONS

Reset System and Evaluate current reagent status (need to do one time only):

1. To reset your VITROS 5600 System, after ensuring testing is complete, perform a Normal Shutdown and start-up of your system.
2. Based on your typical usage, assess which, if any, reagents currently loaded on your system are at risk of exceeding on-analyser stability time prior to being emptied (e.g., low-volume assays or assays with short on-analyser stability time, such as VITROS CRP Slides). **NOTE:** Your usage may be such that all reagents are used prior to exceeding on-analyser stability time and that no packs/cartridges are "at risk."
3. Record the test count of each “at risk” reagent on the system (if any), and then remove the "at risk" reagents from your system. **Note:** MicroTip diluents do not display a test count.
4. Request credit for unused tests by using the Confirmation of Receipt form.

To prevent the occurrence of this anomaly until the new software version is installed:

For All Reagent Types:

a) Ensure that the most recent ADD (i.e., latest DRV#) is installed prior to loading new lots of all reagents by using only the “All Assay Data” load option.

b) Newly opened reagents should be loaded normally using the Load/Unload process. It is not necessary to perform any additional Shutdowns for reagents loaded using the Load/Unload process.

c) To load partially used reagents, *or* full reagents that have been previously loaded on another system, first ensure all testing is complete. Do not use the Load/Unload process button. You must use Manual Load process following the V-docs Manual Load instructions for your system and the additional instructions below.

Manually Loading MicroSlide Cartridges:

1. In Reagent Management, use the Manual Load process. Ensure that all information on the Manually Load Cart dialogue screen is complete and accurate for each cartridge loaded.
2. Touch the Status button on Reagent Management screen.
3. *When the reagent inventory process has been completed,* return to the System Status screen and immediately perform Normal Shutdown, and then start-up your VITROS 5600 System.

Manually Loading Reagent Packs (MicroWell, MicroTip, Diluents):

IMPORTANT NOTE: To load partially used packs, packs used on another VITROS System, and packs that have been removed from the same system for any reason (including to remove "Bubbles"), always use the Manual Load Process, specifying the barcode, shelf expiration and open date when prompted to do so.

On the Reagent Management screen, use the Manual Load process. Ensure that all information on the Manually Load Pack dialogue is complete and accurate for each pack loaded.

- If any full or partial pack has been previously loaded on the same analyser, the shelf expiration and open dates will automatically be populated once the barcode has been entered. It is **not necessary** to shut down and restart your system.
- If any full or partial pack has not been previously loaded on the same analyser, you must complete the open date on the Manually Load Pack dialogue, return to the System Status screen and immediately perform a Normal Shutdown, and then start-up your VITROS 5600 System.

ADDITIONAL REQUIRED ACTIONS

- Complete and return the Confirmation of Receipt form no later than **November 1, 2018**.
- Post this notification by each VITROS 5600 System in your facility or with your user documentation.
- Please forward this notification if the product was distributed outside of your facility.

Contact Information

In the event reagents are used beyond their specific on-analyser stability times (OAS), the associated test results may be affected. The potential impact to test results that may be observed is obtainable from Ortho Care Technical Solutions Centre.

We apologize for the inconvenience this will cause your laboratory. If you have further questions, please contact your local Ortho representative or our Ortho Care™ Technical Solutions Centre at 1800 5646766.

Questions and Answers

1. **What is "on-analyser stability time"?**

VITROS Reagents all have a specific "on analyser stability time," which is the amount of time the reagent may remain on the analyser to ensure optimal reagent performance. This varies by reagent and is different from the shelf expiration date.

2. **How is the analyser supposed to work with regard to on-analyser stability time?**

   The analyser is intended to keep track of on-analyser stability time regardless of whether a reagent is full or partially used and loaded using the Load/Unload or Manual Load process.

3. **What scenarios can cause the anomaly to occur?**

   Ortho has discovered several scenarios where the open expiration of a reagent may be incorrectly set.

   The scenarios that may cause this issue are dependent on numerous factors, such as the actual supply slot the reagent was loaded into or whether the slot had contained a previous reagent that had the open date manually entered. The scenarios that can cause the anomaly are listed below.

   IMPORTANT to NOTE: The instructions provided under Required Actions will prevent your system from using reagents incorrectly beyond the on-analyser stability time indicated in the Instructions for Use.

Scenario One

If the shelf expiration date for a reagent lot is not supported by the currently loaded ADD, the open expiration date for a partially used reagent of the unsupported lot that is not manually loaded with the open date specified will be incorrectly assigned as if the reagent was full.

Scenario Two

The expiration date for a partially used MicroSlide cartridge will be incorrectly reset to the expiration date of a new cartridge if:

- The slide supply containing the cartridge is re-initialized, ***and***
- After the cartridge is re-inventoried, the slide count is different by more than +/-3 slides compared to the previous count, ***and***
- The same slot previously contained a cartridge that had been manually loaded with the open date manually entered, ***and***
- A shutdown and restart of the system had not been performed since the previous manual load event.

Scenario Three

The open expiration date for a partially used reagent loaded without specifying the date opened will be incorrectly assigned as if the reagent was full and given full on-analyser stability time. This occurs when:

- A MicroSlide cartridge containing a single slide is loaded without specifying the date opened.
- A less than full MicroWell pack is loaded without specifying the date opened, foam, film or bubbles are detected, the pack is removed to eliminate the foam, film or bubbles, and then the pack is reloaded.