

**FIELD SAFETY NOTICE**  
**ACL TOP FAMILY: ACL TOP, ACL TOP CTS, ACL TOP 700, ACL TOP 700 CTS, ACL TOP 700 LAS, ACL TOP 500 CTS AND ACL TOP 300 CTS**

June 2014

Dear Valued ACL TOP Family Customer:

This notification is intended to advise your facility regarding a potential for a sample misidentification on the ACL TOP Family that only occurs following a specific set of steps combined with the inability of the system to read a specific sample rack barcode.

The ACL TOP Family consists of the following models, including part numbers with suffix "R" or "J":

|                 |                |
|-----------------|----------------|
| ACL TOP         | PN 00000280000 |
| ACL TOP CTS     | PN 00000280020 |
| ACL TOP 700     | PN 00000280010 |
| ACL TOP 700 CTS | PN 00000280050 |
| ACL TOP 700 LAS | PN 00000280030 |
| ACL TOP 500 CTS | PN 00000280040 |
| ACL TOP 300 CTS | PN 00000280060 |

**Issue Description and Result Impact**

For this sample misidentification issue to occur, all of the following steps need to occur:

1. A sample rack containing a barcoded sample in Tube Position 1 (Sample A) is positively identified by the instrument when inserted in any instrument sample area track position.




2. If, during removal of this sample rack containing Sample A, the Rack Position 1 Barcode Label (see picture above) is not recognized by the instrument (the instrument does not alert the user of the error); and,
3. A sample rack is inserted into the same instrument sample area track position before the barcode reader is moved by the user or automatically by the instrument; and,
4. The new rack or re-inserted sample rack contains a different barcoded sample (Sample B) in Tube Position 1; and,
5. Finally, the Rack Position 1 Barcode Label is also not recognized by the instrument, then Sample B will be misidentified as Sample A.

Under the above conditions, the sample ID from Sample A will be misassigned to Sample B.

**NOTE:** If all tests for the barcoded sample in Tube Position 1 (Sample A) successfully resulted before Sample B is inserted, then Sample A will result appropriately and Sample B will not be run.

### **Important Workaround Instructions**

Although we believe this is a rare scenario, following the instructions below will prevent the sample misidentification issue from occurring:

1. After removing a sample rack, insert the next sample rack in a different available instrument track position.
2. If there are no available track positions, home the barcode reader before inserting the next sample rack by selecting the “Home Barcode Reader”  icon.

Please share these workaround instructions with your staff and retain a copy of this letter in your files as a record of the notification.

Please contact your local representative with any questions.

We appreciate your prompt attention to this important notification.

Sincerely,



Regulatory Affairs Director