Instrumentation
Laboratory
A Werfen Company

UPDATED FIELD SAFETY NOTICE - LOT REMOVAL
HEMOSIL READIPLASÎIN (20 ml SIZE), PART No. 0020301400,
ORIGINAL LOT Nos. N1166235 AND N0177760
ADDED LOT No. N0278358, N0479057 AND N0479504

October 5, 2017

Dear Valued Hemosll ReadiPlasTin Customer:

This notification expands the scope of the previously sent Updated Field Safety Notice (dated August 2, 2017) to include additional product lots of Hemosll ReadiPlasîin (20 ml Size) as listed below:

Product Name	Part No.	Lot No.	Exp. Date
Hemosll ReadiPlasîin (20 ml Size)	0020301400	**Original Lots under Removal**	
		N1166235	November 30, 2018
		N0177760	January 31, 2019
		Additional Lots under Removal	
		N0278358	February 28, 2019
		N0479057	April 30, 2019
		N0479504	April 30, 2019

NOTES: Your facility would have only received this previous letter if you were shipped the original affected lots of Hemosll ReadiPlasîin (20 ml Size).

A preliminary quality control screening test has been developed and is currently under review to ensure no future lots of Hemosll ReadiPlasîin are released with this performance issue.

Issue Description and Impact

We have received customer complaints of performance issues on an additional lot (N0278358) of Hemosll ReadiPlasîin (20 ml Size), with the same problem reported of increased imprecision, out of range quality controls and prolonged sample results. As a conservative measure, we are also removing Lot Nos. N0479057 and N0479504 from the field at this time based on results from the above mentioned quality control screening test.

In all complaints received, this vial-specific performance issue was detected by running quality controls per labeled insert instructions and good laboratory practice. However, if quality controls are not performed or do not pass tor each vial of reagent, there is a potential risk of reporting an erroneous result.

Mandatory Customer Actions

Based on the expansion of this lot removal to include **Lot Nos. NOZ78358, N0479057 and N0479504,** please take the tollowing ***immediate*** actions:

- **Run** quality controls **with each vial** and **a minimum of every 8 hours** per labeled insert instructions to identify possible vials with the above performance issues until an alternative lot has been received and is ready tor use.

  NOTE: ACL TOP Family and ACL TOP Family 50 Series analyzers can be configured to automatically perform QC at vial change. Reference "Before vial use" under the QC Setup Definition section of On-line Help or contact your IL representative tor assistance.

- **Discard** any vial with failed quality controls. Only use vials where all quality controls are in range.
- **Check** your inventory tor boxes of **Lot Nos. NOZ78358, N0479057 and N0479504** and **add instructions** (copy of this letter) to run quality controls with each via1.
- **Contact** your local representative to convert to an alternative product lot of Hemosll ReadiPlasTin (20 ml size), Part No. 0020301400.
- **Verify** the alternative lot ***immediatelv on receipt*** and then **destroy** any unused boxes of **Lot No. Lot Nos. NOZ78358, N0479057 and N0479504** (in addition to previously notified Lot Nos. N1166235 and N0177760).
- **Share** this information with your laboratory staff and follow your internal procedures.
- **Forward** this notification to all affected locations within your facility.
- **Retain** a copy of this notification tor your records.
- **Complete and return** the enclosed Mandatory Response Tracking Record.

- **Sequestered (reserved) product lots in IL Inventory**

  Customers who have **Lot Nos. N0278358, N0479057 and N0479504 of HemosIL ReadiPlasTin, PN 0020301400,** sequestered in IL inventory, will be converted to an alternative product lot.

  Contact your local representative for assistance.

We appreciate your prompt attention to this expanded Field Safety Notice.

Sincerely,

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