Instrumentation Laboratory
A Werfen Company

FIELD SAFETY NOTICE – LOT REMOVAL
HEMOSIL READIPLASTIN (20 mL SIZE), PART NO. 0020301400, LOT NO. N0670302

February 26, 2018

Dear Valued HemosIL ReadiPlasTin Customer:

This notification is intended to advise your facility regarding performance issues identified with the following product lot of HemosIL ReadiPlasTin:

Product Name	Part No.	Lot No.	Exp. Date
HemosIL ReadiPlasTin (20 mL Size)	0020301400	N0670302	June 30, 2019

- **Issue Description and Impact**

We have received customer complaints of performance issues on **Lot No. N0670302** of HemosIL ReadiPlasTin (20 mL Size), including increased imprecision, out of range quality controls and prolonged sample results.

This vial-specific performance issue for this lot will be detected by running quality controls per labeled insert instructions, as well as good laboratory practice to perform quality controls with each vial. However, if quality controls are not performed or do not pass for each vial of reagent, there is a potential risk of reporting an erroneous result.

IL is actively working to prevent this performance issue from occurring in the future.

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- **Mandatory Customer Actions**

Based on the confirmed performance issues with **Lot No. N0670302,** please take the following ***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 for 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 for assistance.

- **Discard** any vial with failed quality controls. Only use vials where all quality controls are in range.
- **Check** your inventory for boxes of **Lot No. N0670302** and **add instructions** (copy of this letter) to run quality controls with each vial.
- **Contact** your local representative to convert to an alternative product lot of HemosIL ReadiPlasTin (20 mL size), Part No. 0020301400.
- **Verify** the alternative lot ***immediately on receipt*** and then **destroy** any unused boxes of **Lot No. N0670302**.
- **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 for your records.
- **Complete and return** the enclosed Mandatory Response Tracking Record.

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

Customers who have **N0670302** 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 Field Safety Notice.

Sincerely,

[redacted]

Carol Marble
Regulatory Affairs Director
Instrumentation Laboratory Co.

ADDENDUM

With reference to the latest information from HSA on the circulation of FSN, please be informed that the Chairman Medical Board and relevant Head of Departments of the facilities need to be aware of the issues pertaining the medical device used in the facility. Kindly circulate the email to the above mentioned parties.

If you have any questions, please contact the Clinical Sales Team at biomed.clinical@biomed-global.com, or 6298 4347.

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URGENT MEDICAL DEVICE REMOVAL

HEMOSIL READIPLASTIN (20 mL SIZE), PART NO. 0020301400, LOT NOS. N1166235 AND N0177760

August 2, 2017

Dear Valued HemosIL ReadiPlasTin Customer:

This notification is intended to advise your facility regarding performance issues identified with the following product lots of HemosIL ReadiPlasTin:

Product Name	Part No.	Lot No.	Exp. Date
HemosIL ReadiPlasTin (20 mL Size)	0020301400	N1166235	November 30, 2018
		N0177760	January 31, 2019

- **Issue Description and Impact**

We recently received customer reports of performance issues with some vials of **Lot Nos. N1166235 and N0177760,** including increased imprecision, out of range quality controls and prolonged sample results.

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 for each vial of reagent, there is a potential risk of reporting an erroneous result.

- **Mandatory Customer Actions**

Based on the confirmed performance issues with **Lot Nos. N1166235 and N0177760**, please take the following ***immediate*** actions:

- **Run** quality controls **with each vial** of **Lot Nos. N1166235 and N0177760 and a minimum of 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 for 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 for assistance.

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- **Discard** any vial with failed quality controls. Only use vials where all quality controls are in range.
- **Check** your inventory for boxes of **Lot Nos. N1166235 and N0177760** and **add instructions** (copy of this letter) to run quality controls with each vial.
- **Contact** IL Customer Service Representative at 1-800-955-9525, Option # 1, to convert to an alternative product lot of HemosIL ReadiPlasTin (20 mL size), Part No. 0020301400.
- **Verify** the alternative lot ***immediately on receipt*** and then **destroy** any unused boxes of Lot Nos. N1166235 and N0177760.
- **Document** the destruction on the Mandatory Tracking Response Record and return the completed and signed form to IL Regulatory at the fax number or e-mail address listed below.
- **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 for your records.
- **Complete and return** the enclosed Mandatory Response Tracking Record.

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

Customers who have **Lot Nos. N1166235 and N0177760** of **HemosIL ReadiPlasTin, PN 0020301400**, sequestered in IL inventory, will be converted to an alternative product lot. Contact IL Customer Service Representative at 1-800-955-9525, Option # 1, for assistance.

- **Mandatory Response Tracking Record**

- Return the completed and signed form after alternative lot receipt and lot destruction to:
  - Fax No.: 781-861-4207

    Or
  - E-mail: ra-usa@ilww.com

- **Contact Information for Questions**

- For technical questions, please contact the IL Technical Support Center at 1-800-678-0710, Option # 2 (ACL Coagulation Products).
- For alternate lot availability questions, please contact your IL Customer Service Representative at 1-800-955-9525, Option # 1.

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IL is actively investigating the root cause of this performance issue to ensure future product lots of HemosIL ReadiPlasTin are unaffected.

We appreciate your prompt attention to this important notification.

Sincerely,

[redacted]

Carol Marble
Regulatory Affairs Director
Instrumentation Laboratory Co.

ADDENDUM

With reference to the latest information from HSA on the circulation of FSN, please be informed that the Chairman Medical Board and relevant Head of Departments of the facilities need to be aware of the issues pertaining the medical device used in the facility. Kindly circulate the email to the above mentioned parties.

If you have any questions, please contact the Clinical Sales Team at biomed.clinical@biomed-global.com, or 6298 4347.

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UPDATED FIELD SAFETY NOTICE – LOT REMOVAL
HEMOSIL READIPLASTIN (20 mL SIZE), PART NO. 0020301400, ORIGINAL LOT NOS. N1166235 AND N0177760
ADDED LOT NO. N0278358, N0479057 AND N0479504

October 5, 2017

Dear Valued HemosIL 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 HemosIL ReadiPlasTin (20 mL Size) as listed below:

Product Name	Part No.	Lot No.	Exp. Date
HemosIL ReadiPlasTin (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 HemosIL ReadiPlasTin (20 mL Size).

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

- **Issue Description and Impact**

We have received customer complaints of performance issues on an additional lot (N0278358) of HemosIL ReadiPlasTin (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.

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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 for 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. N0278358, N0479057 and N0479504,** please take the following ***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 for 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 for assistance.

- **Discard** any vial with failed quality controls. Only use vials where all quality controls are in range.
- **Check** your inventory for boxes of **Lot Nos. N0278358, N0479057 and N0479504** and **add instructions** (copy of this letter) to run quality controls with each vial.
- **Contact** your local representative to convert to an alternative product lot of HemosIL ReadiPlasTin (20 mL size), Part No. 0020301400.
- **Verify** the alternative lot ***immediately on receipt*** and then **destroy** any unused boxes of **Lot No. Lot Nos. N0278358, 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 for your records.
- **Complete and return** the enclosed Mandatory Response Tracking Record.

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- **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,

[redacted]

Carol Marble
Regulatory Affairs Director
Instrumentation Laboratory Co.

ADDENDUM

With reference to the latest information from HSA on the circulation of FSN, please be informed that the Chairman Medical Board and relevant Head of Departments of the facilities need to be aware of the issues pertaining the medical device used in the facility. Kindly circulate the email to the above mentioned parties.

If you have any questions, please contact the Clinical Sales Team at biomed.clinical@biomed-global.com, or 6298 4347.

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FIELD SAFETY NOTICE
HEMOSIL READIPLASTIN (10 mL SIZE), PART NO. 0020301300, LOT NO. N0278177

July 27, 2018

Dear Valued HemosIL ReadiPlasTin Customer:

This notification is intended to advise your facility regarding performance issues identified with the following product lot of HemosIL ReadiPlasTin:

Product Name	Part No.	Lot No.	Exp. Date
HemosIL ReadiPlasTin (10 mL Size)	0020301300	N0278177	February 28, 2019

- **Issue Description and Impact**

We have received customer complaints of performance issues on **Lot No. N0278177** of HemosIL ReadiPlasTin (10 mL Size), including increased imprecision, out of range quality controls and prolonged sample results.

This vial-specific performance issue for this lot will be detected by running quality controls per labeled insert instructions, as well as good laboratory practice to perform quality controls with each vial. However, if quality controls are not performed or do not pass for each vial of reagent, there is a potential risk of reporting an erroneous result.

IL is actively working to prevent this performance issue from occurring in the future.

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- **Mandatory Customer Actions**

Based on the confirmed performance issues with **Lot No. N0278177,** please take the following ***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 product lot of HemosIL ReadiPlasTin or an alternative PT reagent has been received and is ready for 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 for assistance.

- **Discard** any vial with failed quality controls. Only use vials where all quality controls are in range.
- **Check** your inventory for boxes of **Lot No. N0278177** and **add instructions** (copy of this letter) to run quality controls with each vial.
- **Contact** your local representative to convert to an alternative product lot of HemosIL ReadiPlasTin or an alternative PT reagent.
- **Verify** the alternative lot ***immediately on receipt*** and then **destroy** any unused boxes of **Lot No. N0278177**.
- **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 for your records.
- **Complete and return** the enclosed Mandatory Response Tracking Record.

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

Customers who have **N0278177** of **HemosIL ReadiPlasTin, PN 0020301300**, sequestered in IL inventory, will be converted to an alternative product lot or an alternative PT reagent.

Contact your local representative for assistance.

We appreciate your prompt attention to this Field Safety Notice.

Sincerely

[redacted]

Carol Marble
Regulatory Affairs Director
Instrumentation Laboratory Co.

ADDENDUM

With reference to the latest information from HSA on the circulation of FSN, please be informed that the Chairman Medical Board and relevant Head of Departments of the facilities need to be aware of the issues pertaining the medical device used in the facility. Kindly circulate the email to the above mentioned parties.

If you have any questions, please contact the Clinical Sales Team at biomed.clinical@biomed-global.com, or 6298 4347.