



## Product Correction

Urgent - Immediate Action Required

**Cc** Chairman Medical Board and relevant Head of Departments

**Date Issued** July 11, 2019

**Product**

Product Name	List Number (LN)	Lot Number	Expiration Date	UDI Number
MULTIGENT Lithium	8L25-30	71175Y600	31OCT2019	[REDACTED]
		80362Y600	31JAN2020	[REDACTED]
		80201Y600	31JAN2020	[REDACTED]
		80533Y600	30JUN2020	[REDACTED]
		80463Y600	30JUN2020	[REDACTED]
		80424Y600	30JUN2020	[REDACTED]
		80605Y600	30SEP2020	[REDACTED]
		90208Y600	31JAN2021	[REDACTED]

**Explanation** Abbott has received the attached Urgent Field Safety Notice from Sentinel CH. S.p.A, the manufacturer of the MULTIGENT Lithium reagent. Refer to the attached Sentinel Urgent Field Safety Notice.

**Patient Impact** Please refer to the attached Sentinel Urgent Field Safety Notice.

- Necessary Actions**
- Please review the attached Urgent Field Safety Notice from Sentinel CH. S.p.A and follow the required actions.
  - Complete and return the Abbott Customer Reply Form.
  - If you have forwarded the product listed above to other laboratories, please inform them of this Product Correction and provide to them a copy of this letter.
  - Please retain this letter for your laboratory records.

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**Contact  
Information**

If you or any of the health care providers you serve have any questions regarding this information, U.S. Customers, please contact Customer Service at 1-877-4ABBOTT (available 24 hours a day, 7 days a week). Customers outside the U.S., please contact your local area Customer Service.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online (<http://www.fda.gov/MedWatch/report.htm>), by mail (<http://www.fda.gov/MedWatch/getforms.htm>), by phone (1-800-332-1088), or by fax (1-800-FDA-0178).

If you have experienced any patient or user injury associated with this Field Action, please immediately report the event to your local area Customer Service.

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**Date Issued** July 11, 2019

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Product Name	List Number (LN)	Lot Number	Expiration Date	UDI Number
Alinity c Lithium Reagent Kit	08P5320	80553Y600	31JUL2019	[REDACTED]
		80444Y600	31JUL2019	[REDACTED]
		80625Y600	30NOV2019	[REDACTED]
		90224Y600	29FEB2020	[REDACTED]

**Explanation** Abbott has received the attached Urgent Field Safety Notice from Sentinel CH. S.p.A, the manufacturer of the Alinity c Lithium Reagent Kit. Refer to the attached Sentinel Urgent Field Safety Notice.

**Patient Impact** Please refer to the attached Sentinel Urgent Field Safety Notice.

**Necessary Actions**

- Please review the attached Urgent Field Safety Notice from Sentinel CH. S.p.A and follow the required actions.
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