



## Urgent Field Safety Notice Product Correction

Immediate Action Required

**Date Issued** December 14, 2017

**Product**

Product Name	List Number	Lot Number	UDI
ARCHITECT DHEA-S Reagents	8K27-20	01316K000	(01) 00380740017446 (17) 180204 (10) 01316K000 (240) 8K2720
		01217A000	(01) 00380740017446 (17) 180413 (10) 01217A000 (240) 8K2720
		02217D000	(01) 00380740017446 (17) 180624 (10) 02217D000 (240) 8K2720
		04117H000	(01) 00380740017446 (17) 181125 (10) 04117H000 (240) 8K2720
ARCHITECT DHEA-S Reagents	8K27-25	01216K000	(01) 00380740017453 (17) 180204 (10) 01216K000 (240) 8K2725
		01117A000	(01) 00380740017453 (17) 180413 (10) 01117A000 (240) 8K2725
		02217C000	(01) 00380740017453 (17) 180617 (10) 02217C000 (240) 8K2725
		02317D000	(01) 00380740017453 (17) 180624 (10) 02317D000 (240) 8K2725
		02417D000	(01) 00380740017453 (17) 180624 (10) 02417D000 (240) 8K2725
		00517F000	(01) 00380740017453 (17) 180902 (10) 00517F000 (240) 8K2725
		02817H000	(01) 00380740017453 (17) 181021 (10) 02817H000 (240) 8K2725

**Explanation**

The purpose of this letter is to inform you of a product correction for the ARCHITECT DHEA-S assay and to provide instructions on what actions your laboratory must take.

Abbott has identified that falsely elevated results may be obtained when using the ARCHITECT DHEA-S assay with **samples from infants up to 60 days old**. The specific cause of the elevated results is currently under investigation. Although falsely elevated results have only been observed with samples from infants up to 60 days old, the Expected Values representative data for children up to 10 years old provided in the ARCHITECT DHEA-S reagent insert should not be used as these reference ranges are being reviewed as part of the investigation.

All in-date lots of current reagent inventory are impacted.

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**Patient  
Impact**

There is a potential for falsely elevated ARCHITECT DHEA-S results to be generated when using the ARCHITECT DHEA-S assay with **samples from infants up to 60 days old**. Internal studies resulted in 93% of the samples from infants up to 60 days old were outside the recommended reference ranges stated in the package insert. The internal studies confirmed falsely elevated ARCHITECT DHEA-S results are not generated for samples from infants over 60 days old.

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**Necessary  
Actions**

- 1) **Immediately** discontinue use of the ARCHITECT DHEA-S assay with samples from infants up to 60 days old.
  - 2) **Immediately** discontinue use of the ARCHITECT DHEA-S reagent insert Expected Values representative data for children up to 10 years old.
  - 3) Please review this letter with your Medical Director and follow your laboratory protocol regarding the need for reviewing previously reported patient results.
  - 4) 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.
  - 5) Please complete and return the Customer Reply Form.
  - 6) 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.

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