

**URGENT FIELD SAFETY NOTICE
AMH Gen II ELISA (REF A79765)**

Part Number	Kit Lot Number
A79765	All Lots \leq 326119

Dear Beckman Coulter AMH Gen II ELISA Customer,

Beckman Coulter is following up on a field safety corrective action for the product listed above. This communication is a follow up to the Urgent Field Safety Notice letter FSN-20434-2, dated 13 June 2013. This letter contains important information that needs your immediate attention regarding the measurement of Anti-Müllerian Hormone (AMH) using the AMH Gen II ELISA kit.

ISSUE:

Beckman Coulter has confirmed that undiluted test samples measured with the AMH Gen II ELISA kit may generate results that are lower than expected, due to interference from complement.

IMPACT:

- The test results for undiluted AMH samples may be lower than expected.
- Based upon our internal testing, an approximately seventy percent (70%) magnitude in shift was observed for samples that are tested within 1-2 hours after they are drawn. The percent shift observed is dependent upon the samples and the sample storage conditions tested. Freshly drawn or freshly frozen samples have a higher risk of complement interference. As samples age, the interference from complement decreases.
- Control values are not affected.

ACTIONS/RESOLUTION:

- In the previous 13 June 2013 notification, FSN-20434-2, Beckman Coulter informed you to:
 - Discontinue use of all AMH Gen II ELISA kits with lot numbers less than or equal to 326119.
- The product instructions provided in this letter supersede the instructions from the previous notifications, FSN-20434 and FSN-20434-2.
- The AMH Gen II ELISA kit procedure has been modified, and you can now use the current AMH Gen II ELISA kit (REF A79765) with the revised AMH Gen II ELISA Instructions for Use (IFU – REF A92268D) that is enclosed with this notice. The revised test procedure includes an additional assay step that you must perform before you add AMH Gen II Calibrators, controls, or AMH samples to the microplate. This additional step will eliminate the complement interference.



EVALUATION PROTOCOL:

You may use the following protocol to determine if this issue affects the AMH sample testing in your laboratory.

- Obtain a set of AMH samples **according to your normal sample handling procedure and as specified in the current IFU**. It is recommended to test at least 40 samples. Be sure that there is sufficient volume of each sample to run in duplicate in two separate assays.
- Test the samples with the AMH Gen II ELISA assay by following the directions provided in the current AMH Gen II ELISA IFU.
- Test the same set of samples with the AMH Gen II ELISA assay by following the directions provided in the revised AMH Gen II ELISA IFU (REF A92268D). The revised IFU is enclosed with this notification.
 1. Before adding sample to the AMH Gen II ELISA microplate, you must prepare all calibrators, controls, and samples with the **AMH Gen II Assay Buffer** (REF A56021) as follows.
 2. In a sample tube, prepare 1 part of each calibrator, control, or test sample respectively (including diluted pediatric male samples) with 5 parts AMH Gen II Assay Buffer (for example, 60 μ L calibrator, control, or sample + 300 μ L AMH Gen II Assay Buffer).

NOTE: This is a preparation of the AMH Calibrators, controls and test samples with the AMH Gen II Assay Buffer. No dilution factor is required.
 3. Mix thoroughly.
- Within one hour, pipet 120 μ L of the premixed calibrators, controls and samples to the appropriate wells using a precision pipette. Compare the test results that you obtained using both methods to evaluate the effect of the identified issue on your AMH samples.
- If the study results suggest that AMH samples within your test population are affected, use the revised AMH Gen II ELISA IFU to repeat testing as required.

NOTE: This revised procedure restores the ability to dilute AMH clinical samples prior to running the assay. You should dilute any sample that reads higher than the highest calibrator with sample diluent and test the diluted sample again. For pediatric male samples, dilute 1 part sample with 9 parts sample diluent before testing.

The national competent authority has been informed of this field safety corrective action.

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected products listed in the table to another laboratory, please provide a copy of the letter to them.



Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact your local Beckman Coulter representative.

We apologize for the inconvenience that this has caused your laboratory.

Sincerely,

A handwritten signature in black ink that reads "Scott Cundy".

Scott Cundy
VP, Quality and Regulatory Affairs

Enclosures: Revised Instructions for Use & Response Form

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