**5/30/2019 Call with Beckman re: Class I FDA recall DxH 800, DxH 600, DxH 900**

Continuation of previous recall July 2018 – incr in reports of erroneous high plt counts

Class I Recall because less than 100% compliance of acknowledgement of initial recall and FDA wants to further investigate the software patch.

Retrospective data review: rate of occurrence: 0.0026% over 1.7 million sample runs over 21 month period; flagging software identifies 100%

Correlation between complaints and software enhancement V3.1.1 on DxH 800 – Clear RBC Aperture

This feature intentionally introduces air to clear aperture – some instruments fail to remove air pockets, which blocks aperture.

**Customer Actions:**

1. Respond to Beckman using the Customer Response Form.
2. Install flagging software enhancement (software patch)
3. Stop using Clear RBC Aperture feature.
4. Also need to do additional work itemized in the Beckman Customer Letter **for flagged results** on instruments that are part of the recall. Justification for limiting follow-up to flagged results is provided by Peter Soltani from Beckman in a separate document.

* Run samples on an instrument not subject to this recall to confirm the platelet results.
* If an alternative instrument is not available, use the following quality control measures to aid in identification of discrepant platelet results:
  + Perform manual scanning/estimate of platelets on a peripheral smear and compare with instrument results. Note that this method will identify samples with marked to moderate thrombocytopenia but may not identify smaller discrepancies.
  + Repeat testing of samples in a workflow configuration may facilitate the identification of discrepancies. If an erroneous result is detected, review results from adjacent samples, i.e., those tested on the instrument both before and after the erroneous result.
  + Additional instrument and/or LIS features including reference ranges, XM (exponentially-weighted moving average) and delta checks may be informative.
  + Follow your laboratory’s standard operating procedure to confirm unexpected results.
* Communicate to the ordering physicians the need to avoid patient treatment based solely on any single test result, and to interpret all results in the context of other clinical and laboratory features. Physicians should be vigilant when reviewing platelet count results, particularly in patients at risk for thrombocytopenia, such as those with leukemia, certain types of anemia, infection, alcohol abuse, autoimmune diseases, thrombotic microangiopathy, hypersplenism, pregnant patients, patients on chemotherapy, receiving heparin treatment or taking certain medication including quinine, anticonvulsants and sulfonamide antibiotics.
* Consult with your Medical Director to determine if a retrospective review of results is warranted.
* Report any unflagged erroneously elevated platelet counts experienced in your laboratory to Beckman Coulter (contact information is at the end of this letter) and you may also report to the United States Food and Drug Administration (Visit www.fda.gov/medwatch, or call 1-800-FDA-1088).

Question from Shiu-land Kwong (NCAL Quality and Compliance): how do we do patient lookback?

Beckman: **No reported impact to patients, no harm, no reported change in patient management**

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