July 29, 2015

KAISER LAMC TRAINING DOCUMENT:

TO ALL CLS ROTATING IN URINALYSIS:

URGENT MEDICAL DEVICE RECALL

**ISSUE:** iChem velocity system do not maintain the on-board strip stability claim of 5 days of 18-28°c at 20-80% relative humidity as stated in the iChem velocity product labeling.

**IMPACT:** If operating outside the parameter which is 1.0 day for our laboratory, test results may be affected as indicated below:

* FALSE LOW OR FALSE NEGATIVE RESULTS: KETONE, BLOOD
* FALSE HIGH OR FALSE POSITIVE RESULTS: BILIRUBIN, GLUCOSE, LEUKOCYTES
* FALSE HIGH RESULTS: UROBILINOGEN

ASCORBIC ACID, PROTEIN, PH AND NITRITE ARE NOT AFFECTED.

**ACTION:** On board stability on iChem Velocity strips on instrument for KAISER LAMC LABORATORY is **24hours**

* Discard all iChem velocity strips >24 hours on board the instrument
* Desiccants will be replaced in the instrument when last batch of new strips in tube container is consumed.
* Load only the amount of strips you’d estimate will be used during your shift.
* After every new strips are loaded, write/update the date and time (with initial) when the new strips were loaded. Update of change is located on the white board near the instrument.

