

Pasadena Police Department Regional Crime Laboratory

Corrective Action Request Form

Type of Incident:

METHOD INSTRUMENT ANALYST CLERICAL STANDARDS

Describe the incident(s) (be specific regarding events leading to or causing the problem; "N/A" for strictly preventative actions). Incident date(s): **February 9, 2010**

Derek Sanders received the attached letter from Cliniq who provides blood alcohol standards. Derek had noticed that these standards, especially the one that was supposed to be 0.08, was always below what it was supposed to be.

Describe the corrective action taken (how the situation is being addressed; "N/A" for strictly preventative actions):

Derek has never relied on the numbers that they represent their standards to be, so no case work was adversely affected. We should investigate other possible sources for whole blood alcohol controls.

Describe the preventative action taken (what is being done to prevent re-occurrence of the problem or to improve the quality system):

Derek has tried Biorad whole blood standards before and found the same problems. A quality standard for whole blood alcohol may not be available.

Routing (check necessary boxes and obtain signatures):

Section Leader:  Date: 10 Feb 2010
Derek Sanders

Applicable Analyst:  Date: 10 Feb 10
Sebastian Frommhold

QA Manager:  Date: 2-10-10
Claudia Busby

Laboratory Director:  Date: 10 Feb 10
Pamela J. McInnis

January 12, 2010



CUSTOMER NOTIFICATION

**LiquiSp_x Whole Blood Ethanol Control
LiquiSp_x Whole Blood Volatile Control
Product Storage Update**

To Whom It May Concern:

Cliniqa Corporation has recently become aware of an issue involving our Whole Blood Ethanol Kit Catalog No.'s 93211,93212,93213 and Volatile Control Kit, Catalog No.'s 93221 and 93222. Stability data indicates customers may see a decrease in concentrations by as much as 15% over time. We have moved all inventories from refrigerated to frozen storage to arrest this process.

The ranges provided in the package insert are intended only as a guideline. Each laboratory should establish their own acceptable ranges and tolerance limits based on their test system. If you see a drop in control recovery, please contact Cliniqa Technical Support at 1-800-728-5205.

Effective Date:

These changes are effective immediately.

Action Items:

Laboratory personnel should account for all lots currently in their inventory and move those in question to frozen storage immediately. Please conduct any necessary training determined by your lab.

Cliniqa greatly appreciates your support and patience in this matter. We are committed to providing quality products and customer support. If you have any questions regarding this information, please contact our Technical Support Department at 1-800-728-5205.

Sincerely,

Dawn Gast
Director of Quality and Regulatory
Cliniqa Corporation