DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax:(973) 331-4969 Industry Information: www.fda.gov/oc/industry	07/19/2010 - 08/11/2010* FEI NUMBER 2245578

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Gregory Arnsdorff, President

FIRM NAME	STREET ADDRESS
Abbott Point of Care Inc.	400 College Rd E
CITY, STATE, ZIP CODE, COUNTRY Princeton, NJ 08540-6607	TYPE ESTABLISHMENT INSPECTED Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

A violation of the FD&C Act involving a device which might present a risk to health was not reported to FDA.

Specifically, the firm failed to report to FDA under Part 806 the following field actions:

Field Action Numbers	Field Action Initiation Dates	Product Names	Lot Numbers	Quality Issues
APOC30AUG2006	9/11/2006	i-STAT G3+ Cartridges	Multiple lots	• Cartridges difficult to fill.
APOC06FEB2008	January 2008	i-STAT CTnl i-STAT CK-MB i-STAT BNP Cartridges	Multiple lots	• Cartridges would not fill. • Cartridge labels or channels appeared discolored. • Cartridges had fluid visible in the channels. • Cartridges packaging appeared distended.

OBSERVATION 2

An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Specifically, the following malfunction MDR events were reported to FDA later than 30 calendar days after the day the firm

received or otherwise became aware of the information.

MDR Numbers	Complaint Open Dates	MDR Filed Dates	Days After Initial Information Received
2245578-2007-00031	4/13/2007	8/31/2007	~140 days
2245578-2008-00052	7/3/2008	8/8/2008	~36 days
2245578-2009-00033	6/29/2009	10/1/2009	~94 days
2245578-2009-00044	10/29/2009	12/7/2009	~39 days

OBSERVATION 3

Process validation activities and results have not been adequately documented.

Specifically, the following Printed Circuit Board (PCB) cleaning processes were not adequately validated and documented:

A. The Performance Qualification of the i-STAT Assy, Simulator, PCB Cleaning, Document No. VAL-0027-PQ, Revision A, Final Approval Date 11/14/08, and the Performance Qualification of the i-STAT PCB Cleaning, Document No. VAL-0080-PQ, Revision A, Final Approval 11/14/08, both identified two User Requirement Specifications (USR's) as follows:

1. The cleaning process shall remove (b) (4) from the simulator board. (USR-1)
2. The cleaning process shall remove (b) (4) from the simulator board. (USR-2)

The Performance Qualifications were not complete in that there was no data (i.e., visual inspection results) to support or demonstrate that the cleaning processes were effective and have met all User Requirement Specifications. The simulator board cleaning process uses a (b) (4) in combination with a detergent called (b) (4) to clean the simulator boards. The PCB cleaning process is a (b) (4) process which uses a (b) (4) to (b) (4) scrub the boards using an (b) (4) solvent (b) (4) and rinse with (b) (4)

B. The Operational Qualification of the i-STAT PCB Cleaning Process was not complete in that there was no data (i.e., visual inspection results) to support or demonstrate that the drying step of the cleaning process was effective and reproducible. The firm's current PCB Cleaning Workstation Specification No. SW-3545, Revision A, Effective Date 1/24/07, requires that the PCBs be dried with (b) (4)

OBSERVATION 4

A process whose results cannot be fully verified by subsequent inspection and test has not been adequately validated according to established procedures.

Specifically, the protocols for the following process validations did not include or document the acceptance criteria of the qualification.

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A. The Operational Qualification and Performance Qualification of the Environmental Chamber, Document No. VAL-0291-OQ and No. VAL-0291-PQ, Revision A, Final Approval Date 9/22/09. The Environmental Chamber is used to condition up to (b) (4) analyzers, achieving the temperature and Relative Humidity (RH) profile above while maintaining the temperature and RH uniformity within the Chamber that will ensure each analyzer experiences the same environmental conditions throughout the duration of the Environmental Test. The Environmental Test is intended to confirm the analyzer functionality at specific temperature and RH profiles.

B. The Operational Qualification of the Deionized Water System (EQ-0470), Document No. VAL-0232-OQ, Revision B, Final Approval 10/8/09. The circulating Deionized Water System is utilized to provide deionized water to the Cleaning Room to clean and rinse Printed Circuit Boards prior to assembly into device sub-assemblies.

C. The Operational Qualification of the i-STAT Assy, Simulator, PCB Cleaning, Document No. VAL-0027-OQ, Revision A, Final Approval Date 11/13/08, and the Operational Qualifications of the i-STAT PCB Cleaning, Document No. VAL-0080-PQ, Revision A, Final Approval 11/13/08.

OBSERVATION 5

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically, forty-four (44) total complaints were reviewed. Of the forty-four complaints, eight complaints were MDR reportable events and thirty-six complaints were non-MDR reportable events. Of the thirty-six non-MDR reportable events, nine complaints were not adequately evaluated for MDR reportability. The complaints include:

A. Complaint Incident No. 465390, Open Date 7/14/09, Close Date 10/30/09, reported that "303197 would not activate so the customer performed troubleshooting by changing the batteries, 9 volt lithium batteries. The analyzer still would not activate. 15 minutes after the batteries were replaced, the customer removed the batteries once again and they were hot to the touch and had a burning smell to them but no smoke was seen." "Upon arrival, the analyzer was hot to touch...indicating a short condition within the analyzer." The firm evaluated the incident for MDR reportability. The evaluation determined that the device did not malfunction. However, the preliminary complaint investigation suggested that a short condition within the analyzer occurred. The customer complaint was confirmed.

B. Incident Report No. 459865, Open Date 4/26/10, Close Date: 6/16/10, reported that "Customer called back in to say after putting in batteries the analyzer did not power on and it was warm to the touch. Customer states they did not see smoke, but they did smell something as if something was burning. There were no injury to users by this instrument. Instrument is approximately one month old." The firm evaluated the incident for MDR reportability. The evaluation determined that the device did not malfunction. However, the complaint investigation concluded that "The failure of capacitor (b) (4) was the cause of the elevated casing temperature and the burning odor in the complaint analyzer." The customer complaint was confirmed.

C. Incident Report No. 435031, Open Date 7/14/09, Close Date 10/30/09, reported that "Customer stated that a set of 9V Lithium batteries emitted a burning smell, were hot to the touch and the analyzer is not powering up. Customer observed this

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after installing the batteries into the analyzer and then removing them.". The firm evaluated the incident for MDR reportability. The evaluation determined that the device did malfunction. The complaint investigation concluded that a "component (b) (4) on the main board failed and shorted the nine volt supply, which then caused the batteries to become hot to the touch." The customer complaint was confirmed.

D. Incident Report No. 430936, Open Date 6/8/09, Close Date 10/29/09, reported that "Analyzer sn 304383 and battery compartment is warm and smells burnt. Battery type is rechargeable. The analyzer will not activate." The firm evaluated the incident for MDR reportability. The evaluation determined that the device did not malfunction. However, the complaint investigation concluded that "capacitor (b) (4) on the main board had failed and was burned. This caused a short of the 9 volt battery pack and caused it to become hot to the touch." The customer complaint was confirmed.

E. Incident Report No. 423226, Open Date 3/16/09, Close Date 6/9/09, reported that "Customer has an I- Stat 1 analyzer serial number 327564 that is overheating. Customer is using 9V Ultralite DuracelI battery. No one was harmed." The firm evaluated the incident for MDR reportability. The evaluation determined that the device did malfunction. The complaint investigation concluded that "an APOC operator incorrectly positioned the keypad flex cable, and caused a short of the 9 volt batteries to ground. This resulted in the case of the analyzer to become heated." The customer complaint was confirmed

F. Incident Report No. 416610, Open Date 12/23/08, Close Date 10/23/09, reported that "Analyzer serial number 313691 is hot to the touch and so are the batteries." The firm evaluated the incident for MDR reportability. The evaluation determined that the device did not malfunction. However, the complaint investigation concluded that "the battery carrier shorted the nine volt batteries and caused the elevated temperatures at the battery and on the analyzer." The customer complaint was confirmed.

G. Incident Report No. 410603, Open Date 10/21/08, Close Date 1/21/09, reported that "Istat serial number 327914 will not retain charge and beeame hot to touch after popping sound occurred. This did not result in any injuries." Furthermore, it documented that the battery started to smoke and battery is now unusable. The firm evaluated the incident for MDR reportability. The evaluation determined that the device did malfunction. The complaint investigation stated that the analyzer was not powering up and was hot to touch due to a burnt component (b) (4) found on the main PCB. The customer complaint was confirmed.

H. Incident Report No. 405926, Open Date 8/13/08, Close Date 1/21/09, reported that "Customer called with analyzer serial number 310548 that won't power up, and that the rechargeable batteries were 'hot to the touch'; she's replaced the batteries with batteries from a working analyzer, and it still will not power up." The firm evaluated the incident for MDR reportability. The evaluation determined that the device did not malfunction. However, the complaint investigation concluded that a "component (b) (4) on the main board failed and shorted the nine volt supply, which then caused the battery pack to become hot to the touch". The customer complaint was confirmed.

I. Incident Report No. 405515, Open Date 7/15/08, Close Date 2/11/09, reported that "Battery issue/get too hot." The firm evaluated the incident for MDR reportability. The evaluation determined that the device did not malfunetion. However, the complaint evaluation stated that the analyzer was undergoing repair when it was noticed that it was getting hot. It also stated that the device was a non conforming unit and that it did "fail production".

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Kinh Q. Mac, Investigator KQM	08/11/2010

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OBSERVATION 6

Procedures to control environmental conditions have not been adequately established.

Specifically, the firm's Environmental Specification for Deionized Water (DIW), Document No. ES-4063, Revision C, Effective Date 10/6/09, does not identify the "QC Methods" required for the monitoring of Total Organic Carbon (TOC) in the deionized water, including remedial actions for any out-of-specification results tested. The current TOC limit is (b) (4) ppb. Deionized water is used for cleaning the (b) (4) and the Printed Circuit Boards such as the (b) (4) board and the (b) (4) board.

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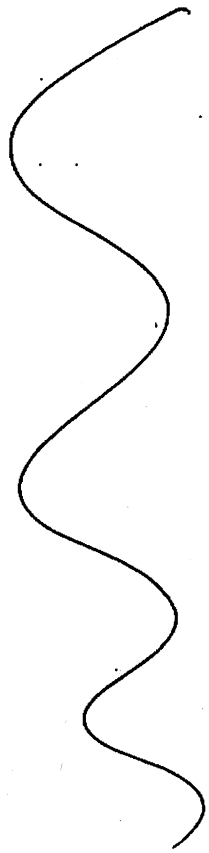
Observation Annotations

Observations intentionally left blank.

*** DATES OF INSPECTION:**
07/19/2010(Mon), 07/20/2010(Tue), 07/21/2010(Wed), 07/22/2010(Thu), 07/27/2010(Tue), 07/28/2010(Wed), 07/29/2010(Thu), 08/03/2010(Tue), 08/05/2010(Thu), 08/06/2010(Fri), 08/11/2010(Wed)



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