DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax: (513) 679-2772 Industry Information: www.fda.gov/oc/industry	03/29/2010 - 04/22/2010* FEI NUMBER 2419955

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: William A. Richardson, Director of Technical Operations

FIRM NAME	STREET ADDRESS
MP Biomedicals Diagnostics Division	29525 Fountain Pkwy
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Solon, OH 44139-4351	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 process whose results cannot be fully verified by subsequent inspection and test has not been validated and approved according to established procedures.

Specifically, the firm performs foil bag sealing using two different foil bag sealers. The sealing process is used to protect products such as (b) (4) tubes, (b) (4) tubes, (b) (4) Plates and Blood spots from moisture which can adversely affect the products.

The firm has not validated either sealer for variables such as time, temperature, or pressure. Additionally, the operating parameters are not recorded for each batch.

Additionally, the firm has identified other processes which have not been validated to include mixing, filling, plate coating, tube coating and cleaning.

The firm also performs lyophilization on some components within IVD kits. These are typically tracers and antibodies within the (b) (4) (b) (4) and Insulin IVD test kits. This process has not been adequately validated as numerous out of specification results were found in the validation data of the (b) (4) test kits without being addressed by the firm. For example, one of the parameters tested for (b) (4) test kits is non specific binding (NSB) which is similar to "background noise". The validation protocol specifies that this value should be (b) (4). A review of data results showed that 40 out of 119 values (34%), were out of specification without being addressed by the firm.

OBSERVATION 2

Complaints involving the possible failure of a device to meet any of its specifications were not investigated where necessary.

Specifically, 4 out of 30 (13%) complaint files reviewed had not been fully investigated to include:

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	Benjamin J Dastoli, Investigator Benjamin J Dastoli	04/22/2010

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1) Complaint PI0912 was received on 10/29/09 involving B12/Folate IVD kits. The complaint was regarding elevated folate counts when using (b) (4) Control lot number 73180. These controls are not supplied with the kits and are not manufactured by the firm. The firm does run assays to determine the control values and reports these back to the OEM.

The firm's investigation showed that the data originally supplied to Bio-Rad was inaccurate which can lead to mis-assignment of target control values. The firm did not perform a risk assessment for this situation, did not evaluate this situation for a potential correction and removal, and did not notify the OEM of the incorrect values.

2) Complaint PI0811 was received on 8/19/08 involving Insulin kits. The kit normally comes with 6 different sets of standards used to establish a data curve. The customer found that there were no #5 standards included with the kit and two #6 standards were included. A total of 40 kits were involved.

The firm's investigation of inventory found discrepancies in totals which supported the complaint. The firm did not perform a risk assessment for this situation and did not evaluate this situation for potential corrective actions.

3) Complaint PI0801 was received on 1/16/2008 involving (b) (4) kits. The complaint was regarding poor results using the kits. 4) Complaint PI0802 was received on 1/22/2008 and involved the same issues with the same lot of TSH.

The firm's in-house investigation regarding the standards in the kit did not identify any issues. The firm decided to destroy the 8 sets of standards remaining in inventory since no explanation was identified for these two similar complaints. The firm did not perform a risk assessment for this situation and did not evaluate this situation for potential corrective actions.

OBSERVATION 3

Procedures for acceptance or rejection of finished device production runs, lots, or batches were not complete.

Specifically, as part of the final release for IVD test kits (containing calibrators, reagents, washes, etc), the firm usually runs low, middle and high values of controls. The firm runs the tests in triplicate and "averages" the results. A review of 30 release records of Phenylalanine showed that in 17 of the records (57%) one of the three values was OOS. The firm did not conduct a failure investigation or have a clear reason for acceptance. The firm "averages" all three values (including the OOS results) which results in a final value which is within specification.

Also, when the firm is establishing values for their calibrators (used to create a standard curve); the firm routinely subjectively removes data points which it deems to be outliers without performing any type of investigation or explanation.

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OBSERVATION 4

The device history record does not include complete acceptance records that demonstrate the device is manufactured in accordance with the device master record.

Specifically, 4 out of 17 (24%) device history records (DHR) for Phenylalanine kits showed errors or discrepancies which were not adequately addressed as described below.

The DHR for lot MPHK0921 of Phenylalanine shows discrepancies in the bulk reconciliation form for Reagent B. Also, the firm measured (b) (4) of neutralizing solution during an in-process filling weight check which has an upper tolerance limit of (b) (4) These deviations were not addressed in the DHR.

The DHR for lot MPHK0927W of Phenylalanine has errors regarding bulk reconciliation for Reagent B and for total bottles filled for Reagent B. These errors were not addressed in the DHR.

The DHR for lot MPHK0909 of Phenylalanine shows an in-process filling weight check of Reagent A of (b) (4) where the upper limit is (b) (4) . This deviation is not addressed in the DHR.

The DHR for lot MPHK0915 of Phenylalanine shows 2 calibration standard data results were deleted without explanation or clear acceptance.

Errors regarding the reagents and calibration standards found in these records affect multiple lots of Phenylalanine, as identical lots of these components are used in numerous finished IVD kits.

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Observation Annotations

Observation 1: Promised to correct.
Observation 2: Promised to correct.
Observation 3: Promised to correct.
Observation 4: Promised to correct.

*** DATES OF INSPECTION:**
03/29/2010(Mon), 03/30/2010(Tue), 03/31/2010(Wed), 04/01/2010(Thu), 04/05/2010(Mon), 04/06/2010(Tue), 04/09/2010(Fri), 04/13/2010(Tue), 04/20/2010(Tue), 04/21/2010(Wed), 04/22/2010(Thu)

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