DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Avenue, Suite 600 Minneapolis, MN 55401 (612) 334-4100 Fax:(612) 334-4134 Industry Information: www.fda.gov/oc/industry	01/08/2015 - 01/20/2015* FEI NUMBER 2244574

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Jonathan M. Sahin, Director of Operations

FIRM NAME	STREET ADDRESS
Life Technologies Corporation	9099 N. Deerbrook Trail
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Brown Deer, WI 53223-2475	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 WE OBSERVED:

OBSERVATION 1

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, your firm evaluated complaint records PR ID 162312, PR ID 139502, and PR ID 135598 and determined that a medical device report was required to be submitted to FDA as documented in the respective complaint records. Your firm failed to follow your internal procedure "Medical Device Reporting", SOP 0003151 in that you failed to submit the medical device reports within 30 days of becoming aware of the malfunction of incorrect labeling which could cause a mis-type of a false negative test result.

For example,

a. Complaint PR ID 162312 was received by your firm on 6/26/2014 for a report of a false negative result (mis-type) in lanes 27 and 39 for the DPB1*33:01 allele of the SSP UniTray HLA typing evaluation test kit. Your firm confirmed the false negative test result on 7/2/2014 and failed to submit 5 medical device reports within 30 days of confirming the complaint; the reports were submitted to FDA on 9/5/2014, approximately 60 days after confirmation of incorrect labeling for the test kits which results in a potential mis-type due to the false negative test result.

b. On 9/23/2013, your firm identified several inconsistencies in how alleles are assigned within a sequence pattern of a given amplicon for SSP UniTray, SSP UniTray with TAQ, and AllSet Gold DRB1-15/16 HR SSP HLA typing test kits. As a result, a mis-type of the test result could occur due to the incorrect labeling showing a negative reaction in lane 5 for the DRB1*15:34/54/66 alleles with primer mix R15-05C. Your firm failed to submit medical device report, 2244574-2013-0070, within 30 days of being aware of incorrect labeling for the test kits; the report was submitted to FDA 12/09/2013, 78 days later.

   Additional lots of the test kits were identified as also being impacted on 9/26/2013; your firm submitted the medical device reports on 1/9/2014, 106 days later.

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c. Complaint PR ID 135598 was opened by your firm on 8/30/2013 for an incorrect reactivity assignment which would cause a mis-type for the A32:04 allele in lane 13 of the AllSet Gold ABC HLA typing evaluation test kit. Your firm identified this issue on 8/23/2013 and failed to submit multiple medical device reports within 30 days of becoming aware of this information. The reports were submitted to FDA on 10/2/2013, 12/12/2013, and 12/26/2013.

This is a repeat observation.

OBSERVATION 2

A supplemental report was not submitted to FDA within one month following receipt of information that was not provided when the initial report was submitted.

Specifically, your firm opened PR ID 138058 on 9/27/2013 regarding false positive reactions in lane 78 for C*04 allele of the AllSet Gold ABC HLA typing evaluation test kit which could result in a mis-type. The complaint was confirmed on 10/21/2013 and an initial MDR was submitted on 10/23/2013 which stated that the investigation was ongoing and additional information would be provided in a follow up report. On 10/28/2013, your firm performed additional testing and determined the issue was confined to batch 038 1249868. You reported the supplemental information on 1/24/2014, 89 days after obtaining this information.

OBSERVATION 3

The total number of devices subject to correction or removal actions was not reported.

Specifically, your firm performed 2 correction and removal actions of DNA based HLA typing kits because of mis-typed results in the test kits' labeling and failed to report to FDA the correct number of total affected kits. Per your assessment of the correction and removal actions, mis-typed results could potentially result in a decision to transplant a solid organ that is unknowingly not as compatible as it could be, or potentially rule out consideration of a patient or an organ for a transplant due to the mis-typed result.

Internal #	Recalled Product	Total Kits Shipped	Total Kits Reported to FDA
009-2012	DPB1 SSP UniTray & AllSet Gold DPB1	(b)	302
001-2012	High Res SSP UniTray & AllSet Gold High Res	(b)	545

This is a repeat observation.

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OBSERVATION 4

The names, addresses, and telephone numbers of all domestic and foreign consignees of devices subject to correction or removal actions and number of devices distributed to each consignee were not reported.

Specifically, you failed to notify all consignees who received SSP UniTray and AllSet Gold HLA typing kits that were recalled by your firm as required by your procedure, "Preparation and Sending of a Customer Notification/Field Safety Notice for Recalls" or "Notifications of Reportable and Non-Reportable Recalls to Customers", SOP0003165.

Internal Recall #	Total Consignees Not Reported
007-2014	(b
009-2012	(b
002-2011/001-2012	Unknown

This is a repeat observation.

OBSERVATION 5

Products that do not conform to specifications are not adequately controlled.

Specifically, on 7/02/2014 your firm determined that lot 009 of SSP UniTray and AllSet Gold HLA typing kits were mis-labeled. You failed to quarantine and prevent the distribution of (b affected kits that were available in your inventory which resulted in consignees receiving kits that were mis-labeled.

This is a repeat observation.

OBSERVATION 6

Procedures for corrective and preventive action have not been adequately established.

Specifically, your firm failed to take corrective actions in a timely manner commensurate with risk.

For example,

a. On 6/26/2014, your firm opened complaint PR ID 162312 in regards to a report that the SSP UniTray DPB1 HLA typing test kit was yielding a false negative result in lanes 27 and 39 for the DPB1*33:01 allele. The complaint was confirmed on 7/2/2014 and resulted in a recall of the test kits due to your assessment that this could have the potential to cause a delay in treatment for the patient. Your firm took the following corrective actions:

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- Affected product in available inventory was placed on hold 7/29/2014, 28 days after confirmation of the complaint. As a result of the delay in placing products on hold, (b mis-labeled kits were distributed to consignees;
- A Nonconforming Materials report was opened 8/8/2014, 38 days after confirmation of the complaint;
- Corrective Actions were opened 8/19/2014, 49 days after confirmation of the complaint; and
- A customer notification letter was distributed to affected consignees 8/22/2014, 52 days after confirmation of the complaint.

Additionally, 5 medical device reports were submitted to FDA that exceeded the 30 day timeframe for reporting.

b. On 9/27/2013, your firm opened complaint PR ID 138058 in regards to a report of a weak false positive in lane 78 when tested with a C*04 homozygous sample negative for the mix with the AllSet Gold ABC Lot 038 HLA typing test kit which could cause a potential mis-type. The complaint was confirmed on 10/21/2013. Your firm took the following actions:

- Corrective Actions were opened 3/31/2014, 162 days after confirmation of the complaint;
- Rework plan approved 2/25/2014, 128 days after confirmation of the complaint;
- Health Hazard Evaluation approved 3/10/2014, 141 days after confirmation of the complaint;
- A customer notification letter was distributed 3/11/2014; 142 days after confirmation of the complaint;
- Supplemental information was provided to FDA 1/24/2014, 89 days after receipt of the additional information.

Your firm closed this complaint on 2/28/2014, prior to completion of all corrective actions.

Furthermore, your firm closed all of the CAPA records related to the previous FDA inspection indicating the corrective actions taken to address the observations were effective. The current inspection has identified repeat issues and a lack of objective evidence to support your conclusions of the corrective actions being effective. Your review of corrective actions taken for each CAPA record failed to identify the numerous failures that were identified during this inspection.

This is a repeat observation.

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Observation Annotations

Observation 1:	Under consideration.	Observation 2:	Under consideration.
Observation 3:	Under consideration.	Observation 4:	Under consideration.
Observation 5:	Under consideration.	Observation 6:	Under consideration.

*** DATES OF INSPECTION:**
01/08/2015(Thu), 01/09/2015(Fri), 01/12/2015(Mon), 01/13/2015(Tue), 01/14/2015(Wed), 01/20/2015(Tue)

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