

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0700812	<b>(X3) Date Survey Completed</b> 11/27/2019
<b>Name of Provider or Supplier</b> Campbell Family Prc & Intrnl Med Asocs	<b>Street Address, City, State</b> 10950 Resource Parkway Suite A, Houston, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
<b>D5781</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on a review of environmental records from 2019, patient test logs, and confirmed with interview of facility personnel, the laboratory failed to document corrective action on all days when the room temperature check was documented as out of acceptable range. Findings were: 1. A review of environmental records from July to October 2019 revealed that the laboratory documented 4 of 30 days when the room temperature was out of acceptable range. Acceptable range was documented as 64 - 90. The unacceptable temperature check documentation was: Date Temp (F) 7/26 /19 63 7/29/19 63 8/28/19 63 8/12/19 63 2. Review of the laboratory records revealed no documentation of corrective action on the above days of documented unacceptable</p>

temperature check. 3. Review of the laboratory patient test log revealed the laboratory performed patient testing on the above dates. Refer to patient alias list. 4. An interview of the primary testing person on 11/27/19 at 1207 hours in the office confirmed the above findings.

**D5783**

**CORRECTIVE ACTIONS**  
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:  
A. Based on a review of hematology quality control reports for 2019 and confirmed in interview, the laboratory failed to evaluate all patient test results obtained since the last acceptable quality control run when controls failed to meet the laboratory's established criteria for acceptability for CBC (complete blood count) testing on the Cell-dyn emerald hematology analyzer. Findings were: 1. A review of the hematology quality report for the July to October 2019 revealed quality control failure for the following dates: Date QC 09/16/19 L9238, 09/19/19 L9238 11/19/19 L9238, H9238 11/21/19 L9238, N9238, H9238 2. Corrective action documented on the above dates revealed a bleach maintenance were performed and the controls were rerun with acceptable values. 3. A review of the Cell-Dyn Emerald Operator's Manual (9140855D - June 2010) states "cleaning the system with a bleach solution is performed monthly or as needed when a measurand is repeatedly rejected." 4. Review of the above dates revealed no documentation of evaluation of all patient test results obtained since the last acceptable quality control run when controls failed to meet the laboratory's established criteria. 5. An interview with the primary testing person on 11/27/19 at 1120 hours in the office confirmed the above findings. She stated that she was unaware that she needed to do anything with the patients that were run since the last acceptable QC. B. Based on review of the laboratory's policy, quality control reports from 2019 and confirmed in interview, the laboratory failed to document all corrective actions taken when hematology quality control was outside of established operating parameters. Findings were: 1. A review of the laboratory's policy Laboratory General Policies revealed "all remedial actions (corrective actions) for unacceptable QC must be documented with the following information: date, problem and what course of action was taken to resolve the problem whether or not the problem was resolved, who worked on it." 2. A review of the laboratory's quality control report from July to October of 2019 revealed quality control failures for the following dates without documentation of all corrective actions taken: Date QC 7/05/19 L9154 7/16/19 L9154 7/30/19 N9154 8/06/19 L9154 8/21/19 L9154 9/18/19 L9238 10/1/19 L9238 3. The laboratory was asked for documentation of the corrective actions performed for the above dates. No documentation was provided. 4. Review of the laboratory patient logs revealed the laboratory performed patient testing on the above dates. See patient alias list 5. An interview with the primary testing person on 11/27/19 at 1140 hours in the office confirmed the above findings.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of quality assessment reports and interview, the laboratory quality assessment policies and procedures failed to identify and correct problems identified in analytical systems. Refer to D5781, D5783