

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0700812	<b>(X3) Date Survey Completed</b> 04/18/2018
<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>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policy, review of the laboratory's One World Accuracy accutest proficiency testing records from 2017 and 2018, and confirmed in interview revealed the laboratory failed to have documentation of rotating proficiency testing among all testing personnel for hematology. Findings were: 1. Review of the laboratory General Policies (approved 05/01/1997) revealed under Proficiency Testing Procedure "All laboratory personnel who perform tests on patient specimens participate in PT testing." 2. A review of the laboratory's One World Accuracy accutest proficiency testing records from 2017 and 2018 revealed testing person #1 (TP#1) performed 4 of 4 testing events for hematology. 2017 Hematology 1st event 2017 Hematology 2nd event 2017 Hematology 3rd event 2018 Hematology 1st event 3. An interview with the MA (medical assistant) supervisor on 4/18/18 at 1030 hours in the office confirmed the above findings. She stated she only "trusted" TP#1 to perform the proficiency testing.</p>
<b>D5437</b>	<b>CALIBRATION AND CALIBRATION VERIFICATION</b>

CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's instructions, laboratory records, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions to verify the precision prior to calibration for the Cell Dyn hematology analyzer. Findings were: 1. Review of the Cell-Dyn18 Plus Calibrator assay sheet (350008-3) revealed under instructions for use: "Verify instrument precision." 2. Review of the Pre-Calibration Procedure Checklist (Celly Dyn Emerald Operator's Manual 9140861C, December 2009) revealed "Verify the instrument precision by running a fresh, normal whole blood specimen ten times into PRECISION file...Ensure that CV% results are within the limits as provided in Section 4: Performance Characteristics and Specifications." "MCV %CV Limit 0.8%" 3. Review of the 2017 calibration data records revealed the precision was above the limit of 0.8% for 2 of 4 calibrations performed. 02/28/17 MCV - 1.7 10/26/17 MCV - 1.0 4. An interview with the testing person #1 on 04/18/18 at 1105 hours in the laboratory confirmed the above findings. She stated acknowledged that she doesn't verify the %limits when performing the calibration.

**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:

Based on a review of the laboratory policy, Cell Dyn Emerald hematology quality control reports for 2017, 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. Findings were: 1. A review of the Laboratory General Policies (approved 5/1/1997) revealed "Remedial Actions - Quantitative Tests, when controls do not react as expected, ensure that all reagents, controls, and calibrators are not expired, then: "a) Repeat the control testing. b) Repeat with a new control c) Repeat with a new control with a different lot number d) Calibrate the system and repeat with both the new and old

controls. If acceptable, repeat patient testing and report new patient results." 2. Random review of the Cell Dyn Emerald hematology quality control (QC) for 2017 revealed 3 of 20 days when there were quality control failures. 2/24/17 - corrective action recalibrated on 02/28/17 and QC passed lot L6326, exp 03/10/17 lot N6326, exp 03/10/17 lot H6326, exp 03/10/17 07/17/17 - QC failures; backflush, bleach lot L7128, exp 08/25/17 lot N7128, exp 08/25/17 lot H7128, exp 08/25/17 10/19/17 changed controls; bleached machine, controls passed lot L7217, exp 11/17/17 lot N7217, exp 11/17/17 lot H7217, exp 11/17/17 3. Review of the laboratory records revealed no documentation to show that patients prior to these quality control failures back to the last successful quality control run were evaluated. The last successful quality control was run the morning of 02/23/17, 07/14/17, 10/18/17. Refer to Patient Alias list. 4. An interview with the testing person #1 on 04/18/18 at 1145 hours confirmed the above findings. She was unaware that she needed to remediate to the last good quality control.

**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 the laboratory quality assessment records, review of laboratory procedures, calibration records, the laboratory's quality assessment policies failed to monitor assess and correct problems in analytic systems. Findings were: 1. The laboratory failed to follow the manufacturer's instructions to verify the precision prior to calibration for the Cell Dyn hematology analyzer. Refer to D5437 2. 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. D5783

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's proficiency test records and interview, the laboratory director failed to ensure proficiency sample testing were rotated among all testing personnel for hematology. (Refer to D2007)

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of the CMS form 209, personnel records for 2016 through 2018, and verified by interview, the Technical Consultant failed to perform the competency evaluations for 1 of 7 testing personnel (TP) for the Cell Dyn Emerald hematology analyzer. (TP#1) Findings were: 1. A review of the facility's personnel files revealed 1 of 7 testing personnel (TP #1, hire date 03/23/16) had documentation of an annual 2016 competency assessment performed by TP# 7 on 03/23/16, who did meet the requirements as a technical consultant. Testing person #7 has a high school diploma. 2. An interview with the MA supervisor on 04/18/18at 1015 hours in the office confirmed the above findings. She stated that TP#2 only performed testing and nothing else. key: CMS - Centers for Medicaid and Medicare Services

**D6049**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on review of the laboratory competency records and confirmed in interview, the technical consultant failed to document competency that assessed quality control and preventive maintenance records. For 1 of 7 testing personnel (TP) for the Celly Dyn Emerald hematology analyzer. (TP#2) Findings were: 1. A review of the laboratory competency assessment records revealed a competency assessment was performed for TP#2 (hire date 05/17/17) on 05/19/17 and 11/29/17. 2. Review of the competency assessment for TP#2 for both dates revealed "NA" for "Quality Control testing/recording"; "Instrument Maintenance/function checks." 3. An interview with the MA supervisor on 04/18/18at 1015 hours in the office confirmed the above findings. She stated that TP#2 only performed testing and nothing else.

**D6052**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)(vi)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:

Based on review of the laboratory competency records and confirmed in interview, the technical consultant failed to document competency that assessed problem solving skills. For 1 of 7 testing personnel (TP) for the Cell Dyn Emerald hematology analyzer. (TP#2) Findings were: 1. A review of the laboratory competency assessment records revealed a competency assessment was performed for TP#2 (hire date 05/17 /17) on 05/19/17 and 11/29/17. 2. Review of the competency assessment for TP#2 for both dates revealed "NA" for "Assessment of problem solving skills" and "Problem Solving Skills." 3. An interview with the MA supervisor on 04/18/18at 1015 hours in

the office confirmed the above findings. She stated that TP#2 only performed testing and nothing else.