

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2133040	(X3) Date Survey Completed 07/23/2018
Name of Provider or Supplier Csl Plasma, Inc	Street Address, City, State 2200 N Yarbrough Dr, Suite K, El Paso, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Review of policies and procedures and interview of facility personnel found that the laboratory director failed to approve sign and date procedures available to testing personnel for use in patient testing. Findings included: 1. Review of Policies and Procedures in the management/leadership policy and procedure manual found no documentation of the approval (including signature and date of approval) by the current laboratory director for seven of seven procedures. Procedures were available to testing personnel in a digital format only, which had no written approval by the laboratory director. 2. Interview of the center assistant manager conducted on July 23, 2018 at 12:49 PM confirmed that the procedures had no documentation of approval by the current laboratory director with a hire date effective July 1, 2018..</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observations, review of the Reichert Plasma Protein Refractometer operator's manual, and interview with facility personnel, the laboratory failed to</p>

follow the manufacturer's test system instructions for using distilled or deionized water for calibrating or checking the zero point each day of patient testing for 23 of 23 days between July 1, 2018 and July 23, 2018. The finding included: 1. During a tour of the facilities at 13:01 hours on 7/23/2018, the surveyor observed the following water container in the cabinet where quality control materials were stored: Favorite Arrowhead Nestle Waters "100 percent Mountain Spring Water - 16 servings" 2. Based on review of the Rechart Plasma Protein Refractometer operator's manual (13970000-100, Rev.J 10/2014), on page 7, the manual states the following: "9.0 SETTING ZERO POINT AND VERIFICATION Setting or verifying the zero point should be performed on a daily basis prior to use. Setting the zero point is similar to the 'Tare' function on an analytical balance. To verify the zero point or to reset the zero point, if necessary, follow these steps: Step 1: Action: Ensure that the sample measurement surface and the well are visually clean, residue free and dry. Reference section 8.0 if cleaning is warranted. Step 2: Action: Place distilled or deionized water on the sample measurement surface, ensure that the entire sample measuring surface is covered and that no air bubbles are present." And; On page 11, under Section 12.0 HELPFUL HINTS, the manual states the following: "Verify or if required perform zero set point daily with distilled or deionized water." 3. Based on a review of daily calibrations for Reichert Plasma Protein Refractometer Equipment Number 1970006, the instrument was calibrated with the Mountain Spring water instead of the required distilled or deionized water on the following 23 of 23 days between July 1, 2018 and July 23, 2018: 07/01/2018 07/02/2018 07/03/2018 07/04/2018 07/05/2018 07/06/2018 07/07/2018 07/08/2018 07/09/2018 07/10/2018 07/11/2018 07/12/2018 07/13/2018 07/14/2018 07/15/2018 07/16/2018 07/17/2018 07/18/2018 07/19/2018 07/20/2018 07/21/2018 07/22/2018 07/23/2018 4. In an interview at 13:13 hours on July 23, 2018, the Center Manager confirmed the laboratory had been using the Mountain Spring water instead of distilled or deionized water.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on the laboratory's quality control records from January 2018 through June 2018, manufacturer instructions for the Kova Refractrol quality control material, quality assurance records, laboratory policies and procedures, and staff interview, the laboratory failed to monitor over time the accuracy and precision of quality control material tested on the Reichert refractometers. The findings included: 1. A review of the laboratory's Reichert refractometers quality control records from January 2015 through January 2017 revealed the laboratory evaluated quality control values daily for acceptability, but had no means of monitoring the control over time for each of the 9 refractometers used. 2. The manufacturer's instructions for the Kova Refractrol SP

quality control material, under "Summary and Principle", states: "Good laboratory practice procedures require that stable reference materials be used to verify the accuracy and precision of testing methods and techniques." The laboratory was asked to provide documentation of evaluating the performance of control results over time to assess accuracy and precision and detect trends or shifts in performance. The laboratory offered the Verification Certificate of Published Total Protein Assay Values for KOVA Refractol SP signed 08/16/17 as evidence of review. 3. Quality Control lot numbers used by the laboratory between January 2018 and June 2018 were lot K301820 Expiration 10/2019 (low control) and lot K301815 Expiration 07/2019 (high control) 4. Interview of the Assistant Manager of Quality conducted on July 23, 2018 at 12:49 PM confirmed that the daily acceptability logs are evaluated by the laboratory director periodically but the performance of the quality control material over time was not evaluated.