

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  06D2025384	<b>(X3) Date Survey Completed</b>  07/25/2019
<b>Name of Provider or Supplier</b>  Kfhp Brighton Laboratory	<b>Street Address, City, State</b>  859 S 4th Ave, Brighton, CO	
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>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on the lack of proficiency testing (PT) records and staff interview, the laboratory failed to enroll in an HHS-approved PT program for 2018 in the specialty of chemistry for urinalysis. Findings include: a. The laboratory tests patient urine specimens for urinalysis using the Clinitek Advantus. b. No documentation existed to show that the laboratory had enrolled in an approved PT program for 2018 for urinalysis testing performed in the laboratory. c. On 7-25-19 at about 9:30 a.m., staff stated that the previous laboratory TC failed to order PT material or enroll for all three events in 2018.</p>
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty,</p>

subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.

This CONDITION is not met as evidenced by:  
Based on review of proficiency testing (PT) scores and staff confirmation, the laboratory failed to achieve successful PT performance in 2 of 3 consecutive testing events in the subspecialty of urinalysis in 2017. See D2096

**D2096**

**ROUTINE CHEMISTRY**  
CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:  
Based on review of proficiency testing (PT) scores for 2017, the laboratory failed to achieve successful performance levels of 80% for 2 of 3 consecutive events in the subspecialty of urinalysis for the 1st and 3rd events in 2017. Findings include: Urinalysis, 1st event 2017 = 0% Documentation showed "upload failed - not resubmitted" Urinalysis, 3rd event, 2017 = 0% Documentation showed "not performed"

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
Based on a review of the laboratory's policies, the lack of verification records, and staff interview, the laboratory failed to verify, before patient use on October 11, 2018, the laboratories policy for using a replacement Clinitek Advantus for urinalysis. Findings include: a. On 10-11-18, the laboratory began using a replacement Clinitek Advantus for urinalysis testing of patient specimens. b. Documentation existed that the main facility in Denver had performed validation studies at that site, so that the

instrument could be used as a backup or loaner instrument. c. No documentation existed that the laboratory performed validation studies when this instrument was placed in the laboratory from the main facility. d. Staff stated that no validation documentation could be located at this site for this instrument and this instrument had not been verified before reporting patient results.

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:  
Based on review of the operator's manual, quality assessment (QA) plan, calibration records and staff interview, the laboratory failed to perform calibration verification testing on the Clinitek Advantus urinalysis analyzer when it was moved to this facility as a replacement instrument on 10-11-18 and approximately 1817 tests are performed annually. Findings include: a. The laboratory's quality assessment policy stated that verification and calibration will be performed when an instrument is moved from one location to another. b. Records showed a calibration verification was performed at the main facility in Denver, but no records existed to show any verification activity was performed when the instrument was moved to the laboratory on 10-11-18. c. Staff confirmed that calibration verification of the instrument was not performed when the instrument was moved to the laboratory as a replacement.