

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2109944	(X3) Date Survey Completed 11/21/2019
Name of Provider or Supplier Dsp Health System	Street Address, City, State 230 Independence Road, East Stroudsburg, PA	
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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation of laboratory reagents and interview with testing personnel (TP) #1, the laboratory failed to ensure that Beckman Coulter bicarbonate calibrators 1+2 (2 of 2 bottles) were not used beyond their expiration date. Findings Include: 1. On the day of survey, 11/21/2019, observation of laboratory reagents revealed the laboratory used Beckman Coulter bicarbonate calibrators 1+2 (2 of 2 bottles) used on the Beckman coulter AU480 for the carbon dioxide test had expired 10/12/2019 and were opened for use on 11/17/2019. 2. TP #1 confirmed the expired calibrators above used on 11/21/2019 around 11:10 am.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation of laboratory's thermometers and interview with the testing personnel (TP) #1, the laboratory failed perform maintenance/ calibration on 2 of 2 fisher scientific min/max alarm thermometers from 2017 to the date of survey. Findings Include: 1. On the date of survey, 11/21/2019, while on tour of the</p>

laboratory, 2 of 2 fisher scientific min/max alarm thermometers observed, were due for maintenance/ calibration on: - Large refrigerator: - S/N 6607 - Cat# ACC895REFV - Due July of 2019 - Retains quality controls and calibrators for the Beckman Coulter AcT Diff 2, Access 2 and AU 480. - Mini freezer: - S/N 3285 - Cat# ACC895FREX - August of 2019 - Retains quality controls and calibrators for the Beckman Coulter Access 2 and AU 480. 3. TP #1 confirmed the findings above on 11/21/2019 around 11:15 am.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on, the review of laboratory quality improvement procedure and interview with testing personnel (TP) #1, the laboratory failed to ensure that quality assessment programs are followed and documented to assure the quality of laboratory from 2018 to the day of survey (16 out of 16 months). Findings Include: 1. The Laboratory Quality Management Plan, page 3 of 4 states, "A total quality improvement report is completed monthly by the laboratory manager and presented at the leadership and quality meeting. 2. On the day of survey, 11/21/2019, TP #1 could not provide documentation of quality improvement reports performed on a monthly basis from: - July 2018 to December 2018 (6 of 6 months) - January 2019 to October 2019 (10 of 10 months) 3. TP #1 confirmed the findings above on 11/21/2019 around 11:00 am.

D6034

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:
Based on review of testing personnel qualification records, quality control (QC) records and interview with testing personnel (TP) #1, the laboratory failed to have a technical consultant who meets the qualification requirements to review QC records for the Beckman coulter AU 480, Beckman coulter Access 2 chemistry analyzers and the Beckman coulter AcT Diff 2 hematology analyzer from 07/13/2018 to the date of survey. 1. A letter signed by the LD states " I designate TP #1, MLT, who meets technical consultant qualifications, to review all quality control result reports for DSP Health System Laboratory. 2. On the day of survey, 11/21/2019, review of QC records and TP #1 qualification records revealed, TP #1 does not meet requirement of a TC and was not listed as a TC on the Laboratory Personnel Report (CLIA), form CMS-

209 signed by the LD on 10/11/2019. 3. TP#1 confirmed they do not meet requirements to perform TC responsibilities on 11/21/2019 around 11:00 am.

D6051

TECHNICAL CONSULTANT RESPONSIBILITIES

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

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on review of testing personnel (TP) records, review of American Proficiency Institute (API) 2018 proficiency testing (PT) records and interview with TP #1, the technical consultant (laboratory director) failed to assess the competency of 1 of 2 TP through internal blind testing samples or external PT samples in 2019. Findings Include: 1. On the day of survey, 11/21/2019, review of TP records and API PT records revealed, the laboratory did not assess the test performance of 1 of 2 TP (TP#2) through chemistry PT samples or internal blind testing samples in 2019. 2. TP#1 confirmed the finding above on 11/21/2019 around 9:40 am.