

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2157575	(X3) Date Survey Completed 05/25/2021
Name of Provider or Supplier Bvp Ascension Seton Hays Path	Street Address, City, State 1st Floor Laboratory 6001 Kyle Parkway, Kyle, 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
D5633	<p>CYTOLOGY CFR(s): 493.1274(d)(1)</p> <p>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of individual workload reports and interviews it was determined that the laboratory failed to follow their own written policies and procedures to ensure maximum workload limits were established by the Laboratory Director for five of five testing personnel performing primary screening in cytology between 2019 and 2021. Findings included: 1. Review of the policy SH-10 titled Cytological examinations (policy date March 15, 2019) found under the heading Cytological Examination procedure: "2. The pathologist serves as the primary screener on some cytology cases. a. The pathologist never receives more than the allowable number of slides to be screened per hour. b. All pathologists that serve as primary screener on cases keep a detailed Cytology Workload spreadsheet. c. The pathologist tracks their work throughout the day to ensure they do not go over the maximum workload based on hours worked." Maximum workload reports for each testing person performing primary screening of cytology slides were requested but not provided. 2. Cytology workload spreadsheets for each testing person were requested but not provided. 3. Interview of the Director of Operations conducted on May 25, 2021 at 12:12 PM confirmed that maximum workload reports and cytology workload reports were not available for all testing personnel performing primary screening of Cytology slides.</p>
D5637	<p>CYTOLOGY CFR(s): 493.1274(d)(1)(ii)</p>

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, lack of individual workload reports and interviews it was determined that the laboratory failed to have a written policy/procedures to reassess maximum workload limits at least once every six months for five of five testing personnel performing cytology between 2019 and 2021. Findings included: 1. Review of the policy SH-10 titled Cytological examinations (policy date March 15, 2019) found under the heading Cytological Examination procedure: "2. The pathologist serves as the primary screener on some cytology cases. a. The pathologist never receives more than the allowable number of slides to be screened per hour. b. All pathologists that serve as primary screener on cases keep a detailed Cytology Workload spreadsheet. c. The pathologist tracks their work throughout the day to ensure they do not go over the maximum workload based on hours worked." Maximum workload reports for each testing person interpreting cytology slides were requested but not provided. 2. Cytology workload spreadsheets for each testing person were requested but not provided. 3. Interview of the Director of Operations conducted on May 25, 2021 at 12:12 PM confirmed that maximum workload was not reassessed at least once every six months for five of five testing personnel performing cytology.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of testing personnel files, and interview of facility personnel, the Technical Supervisor failed to evaluate and document personnel competency at least semiannually during the first year the individual tests patient specimens for four of five testing personnel interpreting histopathology and cytology slides. The findings included: 1. Review of personnel files found one of two expected semiannual competency evaluations during the first year of testing for four of five testing personnel documented on a single page for 2019 and 2020. Testing person one had one competency assessment dated 01/24/2020 and one competency assessment dated 01/22/2021. Testing person two(work started 05/24/2020) had one competency assessment dated 01/22/2021. Testing person three (work started 10/23/2020) had one competency assessment dated 01/22/2021. Testing person four had one competency assessment dated 01/24/2020 and one competency assessment dated 01/22/2021. Testing person five had one competency assessment dated 01/24/2020 and one competency assessment dated 01/22/2021. Additional documentation of competency assessments were requested but not provided. 2. Interview of the director of operations conducted on May 25, 2021 at 11:14 AM confirmed that competency assessments had not been performed and documented at least semiannually for the first year of testing for all personnel.

D6130

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(c)(2)(3)

(c) In cytology, the technical supervisor or the individual qualified under 493.1449(k) (2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary.

This STANDARD is not met as evidenced by:

Based on lack of laboratory records and interviews it was determined that the Technical Supervisor failed to establish individual workload limits and to reassess workload limits at least every six months for five of five testing personnel in 2019, 2020 and to the date of the survey in 2021. Refer to D5633 and D5637