

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0943813	(X3) Date Survey Completed 10/09/2018
Name of Provider or Supplier John Q Binhlam, Md Pc	Street Address, City, State 1649 Westgate Circle, Suite 100, Brentwood, TN	
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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on lack of written policy for monitoring exposure of formaldehyde and xylene, review of the material safety data sheet (MSDS) and interview with the office manager, the laboratory failed to perform annual monitoring exposure for formaldehyde and xylene for testing persons. The findings include: 1. Lack of written policy for a monitoring exposure for formaldehyde and xylene was revealed for 2016-2018. 2. MSDS for formaldehyde and xylene states the minimum exposure limits for person working with these chemicals in an 8 hour or short term limit of 15 minutes must be monitored annually. No monitoring documentation was available for 2016-2018 3. Interview with the laboratory office manager on September 9, 2018 at 11:00 am confirmed the laboratory did not monitor formaldehyde and xylene exposure on an annual basis in 2016-2018.</p>
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 the Hematoxylin stain container, review of the chemical</p>

reagent log and interview with the office manager the laboratory failed to ensure the Hematoxylin stain was not expired prior to use for patient testing from September 2017 through October 9, 2018. Findings include: 1. Observation of the Hematoxylin stain revealed the stain was in use beyond the expiration date of September 2017 through October 9, 2018 for patient testing. 2. Review of the chemical reagent log revealed the Hematoxylin stain was in used beyond the expiration date of September 2017 through October 9, 2018 for patient testing. 3. Interview with the office manager on October 9, 2018 at 10:30 am confirmed the Hematoxylin stain was in use beyond the expiration date of September 2017 through October 9, 2018 for patient testing.

D5479

CONTROL PROCEDURES
CFR(s): 493.1256(e)(5)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of chemical reagent logs and interview with the laboratory's office manager the laboratory failed to follow manufacturer's specifications for using Hematoxylin stain beyond the expiration date of September 2018 for Quality Control testing in October 2017 through October 9, 2018. The Findings include: 1. Review of the chemical reagent logs determined the Hematoxylin stain was in use beyond the expiration date of September 2017 for Quality Control testing in October 2017 through October 9, 2018. 2. Interview with the office manager on September 9, 2018 at 10:45 confirmed the Hematoxylin stain was in use beyond the expiration date of September 2017 for Quality Control testing in October 2017 through October 9, 2018.