

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2097656	(X3) Date Survey Completed 09/18/2018
Name of Provider or Supplier American Esoteric Laboratory - Blytheville	Street Address, City, State 1522 North Division, Blytheville, AR	
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
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: Through a review of the Sysmex XS 1000i Operator's Manual, a review of the Humidity-Temperature Log, and interviews with laboratory staff, it was determined the laboratory failed to perform complete blood counts on the Sysmex XS 1000i following the manufacturer's instructions. Survey findings follow: A. The Sysmex XS 1000i Operator's Manual states that the acceptable operating humidity for the instrument is 30% to 85%. B. A review of the Humidity-Temperature Log for January and February 2018 revealed the humidity of the laboratory was unacceptable on 5 of 24 days of testing. There was no action documented to ensure testing was performed within the operating humidity required by the manufacturer. Humidity was outside the manufacturer's operating range of 30% to 85% on the following dates in January and February 2018: 1/4/2018 27%; 2/1/2018 28.3%; 2/2/2018 28.1%; 2/9/2018 27.7%; and 2/12/2018 23.0%. C. In an interview, at 2:48 p.m. on 9/18/2018, laboratory employee #2 (as listed on the form CMS-209) confirmed the Sysmex XS 1000i had been used for patient testing when the laboratory humidity was outside of the manufacturer's operating range.</p>