

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  26D2013888	<b>(X3) Date Survey Completed</b>  02/08/2018
<b>Name of Provider or Supplier</b>  Bioquintex Laboratories, Inc	<b>Street Address, City, State</b>  1221 Se Broadway Dr, Suite A, Lees Summit, MO	
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>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of hematology procedure and interview with the laboratory manager the laboratory failed to follow hematology procedure and run three levels of quality control (QC) each day of patient testing. Findings: 1. Review of hematology QC on 10/24/17 showed eight patients were reported out and two levels of QC was performed. Procedure states three levels of controls will be performed each day of patient testing. 2. Interview with laboratory director on February 8, 2018 confirmed laboratory failed to follow procedure and run three levels of hematology QC each day of patient testing.</p>
<b>D5415</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation of hematology controls and interview with the laboratory</p>

director on February 8, 2018 at 11:30 AM the laboratory failed to include an expiration date on hematology controls.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(d)

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.

This STANDARD is not met as evidenced by:

Based on observation of Vitamin D chemistry controls and interview with the laboratory director the laboratory failed to check for expiration dates on vitamin D controls. Findings: 1. Review of Vitamin D controls showed an open date of 11/30/17 and controls are still in use. Vitamin D controls are good for "4 weeks" according to DiaSorin package insert. 2. Interview with Laboratory director on February 8, 2018 at 11:30 AM confirmed laboratory failed to check expiration dates on vitamin D controls and continued to use controls for patient testing.