

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D2127020	(X3) Date Survey Completed 07/30/2018
Name of Provider or Supplier Trupath Laboratories, Inc	Street Address, City, State 6748 N Franklin Ave, Unit B, Loveland, CO	
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of proficiency testing (PT) scores and laboratory director confirmation, the laboratory failed to achieve successful PT performance in 2 of 3 consecutive testing events in the specialties of chemistry and immunology in 2018. See D2084 and D2096.</p>
D2084	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two</p>

consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of Proficiency Testing (PT) scores and laboratory director confirmation, the laboratory failed to achieve satisfactory performance for the analyte Hepatitis B Core Antibodies (Anti-HBc) in the specialty of Immunology in 2 out of 3 consecutive PT events. Findings include: Anti-HBc 1st Event of 2018: 60% 2nd Event of 2018: 0%

D2096

ROUTINE CHEMISTRY

CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of Proficiency Testing (PT) scores and laboratory director confirmation, the laboratory failed to achieve satisfactory performance for the analyte blood urea nitrogen (BUN) in the specialty of Chemistry in 2 out of 3 consecutive PT events. Findings include: BUN 1st Event of 2018: 40% 2nd Event of 2018: 60%