

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  27D0652531	<b>(X3) Date Survey Completed</b>  03/13/2019
<b>Name of Provider or Supplier</b>  Montana Public Health Laboratory	<b>Street Address, City, State</b>  1400 Broadway, Room B206, Helena, MT	
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>D5791</b>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of Individualized Quality Control Plan (IQCP) documents and staff interview, the laboratory failed to include the Quality Assessment plan in one of one IQCPs reviewed. Findings include: 1. Review of the Bio Rad HIV Geenius IQCP revealed the Quality Assessment plan was not included with the IQCP documentation. 2. In an interview conducted on 03/12/2019 at approximately 1:00 PM, the technical supervisor confirmed a Quality Assessment plan was not written for the Bio Rad HIV Geenius IQCP</p>