

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  27D0409444	<b>(X3) Date Survey Completed</b>  04/14/2021
<b>Name of Provider or Supplier</b>  Beartooth Billings Clinic	<b>Street Address, City, State</b>  2525 North Broadway, Red Lodge, 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>D5473</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of hematology policy manual, laboratory records and interview with the General Supervisor (GS)#1, the laboratory failed to document the intended staining characteristics for each day manual differentials slides were stained with the Hema 3 Stain Set. Findings include: 1. Review of hematology records revealed the laboratory failed to document the staining quality of manual differential slides each day of Hema 3 Stain Set use for years 2019 and 2020. 2. Review of policy # LABH002 procedure lacked how the laboratory would document staining quality control checks on manual differentials slides. 3. Interview on April 14, 2020 at 11:30 AM with GS #1, confirmed the laboratory failed to document staining quality of manual differential slides using Hema 3 Stain Set for years 2019 and 2020.</p>