

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D0991209	(X3) Date Survey Completed 06/08/2023
Name of Provider or Supplier Medscan Laboratory, Inc	Street Address, City, State 1502 13th Ave W Suite 201, Williston, ND	
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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT 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, staff interview, and procedure review, the laboratory failed to label 4 of 4 hematology staining containers (Fixative, Solution I, Solution II, and deionized water) observed. Findings include: 1. Observation at 11:40 a.m. on 06/08/23 showed four filled containers in a sink at the hematology bench with no identifying information. 2. During interview at 11:40 a.m. on 06/08/23, a technical consultant (#1) stated the containers in the hematology sink contained hematology staining solutions and deionized water used for patient testing and confirmed the laboratory had not labeled these containers. 3. Reviewed on 06/08/23, the policy "Peripheral Blood Smear Staining using Hema 3 Staining Solution," dated 01/12/23, stated, ". . . Required Materials: Hema 3 fixative solution Hema 3 Solution I Hema 3 Solution II 4 Coplin Jars . . . Deionized Water . . . Procedure 1. Transfer each solution to a coplin jar . . ." The procedure failed to include a requirement to label the Coplin jars when filling with staining solutions and deionized water.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p>

This STANDARD is not met as evidenced by:

Based on record review, staff interview, and policy review, the technical consultant failed to include the TOSOH chemistry and Sysmex hematology analyzers in the 2022 annual competency evaluations for 2 of 2 testing personnel's (Testing Personnel #1 and #2) annual evaluations completed in 2022. Findings include: 1. Reviewed at 3:15 p.m. on 06/07/23, the 2022 annual competency evaluations for Testing Personnel #1 and #2 lacked evidence of completed competency evaluations for the TOSOH chemistry analyzer and Sysmex Hematology analyzer. 2. Upon request, the laboratory failed to provide evidence of TOSOH chemistry analyzer and Sysmex Hematology analyzer 2022 competency evaluations for Testing Personnel #1 and #2. 3. During interview at 11:15 a.m. on 06/08/23, a technical consultant (#1) confirmed the 2022 competency evaluations for Testing Personnel #1 and #2 did not include the TOSOH chemistry analyzer and Sysmex Hematology analyzer. 4. Reviewed on 06/08/23, the policy "Training and Competency," revised 04/30/19, stated, ". . . competencies will be determined yearly . . . See appendix A for competency sheets. . . ." The competency sheets in appendix A included: XN1000 (Sysmex hematology analyzer) and TOSOH G8 (TOSOH chemistry analyzer).