Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D1057840	11/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Durango Urgent Care, Llc	2577 Main Ave, Durango, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manual, and an interview with testing personnel #1 (TP #1), the laboratory failed to establish and follow a written policy or procedure to assess the competency of personnel in the positions of Clinical Consultant (CC), and Technical Consultant (TC) since the laboratory's last survey on 9/23/2021. The laboratory conducts a total of approximately 2,689 microbiology tests, approximately 1,000 chemistry tests, and 1,000 hematology tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual revealed that the laboratory failed to establish and follow a written policy or procedure to assess the competency of one out one of the clinical consultants (CC), and one out of one of the technical consultants (TC) listed on the CMS-209 Form. The laboratory conducts a total of approximately 2,689 microbiology tests, approximately 1,000 chemistry tests, and 1,000 hematology tests annually. 2. Based on an interview with testing personnel #1 (TP #1), on November 15, 2023, at approximately 10:00 AM, confirmed that the laboratory failed to assess the competency of or establish a written policy or procedure for assessing the competency of personnel in the positions of CC, and TC. The laboratory conducts a total of approximately 2,689 microbiology tests, approximately 1,000 chemistry tests, and 1,000 hematology tests annually.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manual, and an interview with testing personnel #1 (TP #1), the laboratory failed to have written procedures available to, and followed by laboratory personnel for the Cepheid SARS CoV-2/Flu A&B/RSV plus assay, the Cepheid Strep A assay, Urinalysis, or Pregnancy (HCG) testing since the last survey was performed on 9/23/2021. The laboratory conducts a total of approximately 2,689 microbiology tests, and approximately 1,000 chemistry tests annually. Findings include: 1. A review of the laboratory's policies and procedures manual revealed that the laboratory failed to have a written procedures available to and followed by laboratory personnel for the Cepheid SARS CoV-2/Flu A&B/RSV plus assay, the Cepheid Strep A assay, Urinalysis, or Pregnancy (HCG) testing since the last survey was performed on 9/23/2021. 2. An interview with testing personnel #1 (TP #1) at approximately 11:45 AM, on November 15, 2023, confirmed that the laboratory failed to have written procedures available to and followed by laboratory personnel for the Cepheid SARS CoV-2/Flu A&B/RSV plus assay, the Cepheid Strep A assay, Urinalysis, or Pregnancy (HCG) testing since the last survey was performed on 9/23/2021.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the laboratory's daily temperature record, a review a review of the laboratory's policies and procedures, and an interview with testing personnel #1 (TP #1), the laboratory failed to establish and document the acceptable temperature range of the room storing pregnancy (HCG), urinalysis, Streptococcus Group A, and Cepheid SARS CoV-2/Flu A&B/RSV plus testing reagents at least daily since the last survey was conducted on 9/23/2021. The laboratory conducts approximately 2,689 microbiology tests, and approximately 1,000 chemistry tests annually. Findings include: 1. A review of the laboratory's daily temperature record revealed that the laboratory failed to establish and document the acceptable temperature range of the room storing the pregnancy (HCG), urinalysis, Streptococcus Group A, and Cepheid SARS CoV-2/Flu A&B/RSV plus testing reagents at least daily. 2. A review of the laboratory's policies and procedures manual revealed no policy or procedure was written for documenting room temperature. 3. An interview with testing personnel #1 (TP #1) at approximately 11:15 AM on November 15, 2023, confirmed that the laboratory did not have a written policy or procedure for documenting room temperature, and did not establish or document the acceptable temperature range of the room storing the pregnancy (HCG), urinalysis, Streptococcus Group A, and

	Cepheid SARS CoV-2/Flu A&B/RSV plus testing reagents at least daily since the last survey on 9/23/2021.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a records review, a review of the laboratory's policies and procedures, and an interview with testing personnel #1 (TP#1), the laboratory failed to establish a policy or perform and document the calibration verification for the Chem 8+ panel on the Abbott iStat instrument since the last survey was conducted on 9/23/2021. The laboratory performs approximately 1,000 chemistry tests annually. Findings include: 1. Based on a records review, the laboratory failed to perform and document calibration verification for the Chem 8+ panel on the Abbott iStat instrument since the last survey was conducted on 9/23/2021. 2. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to establish a policy for performing calibration verification on the Chem 8+ panel on the Abbott iStat instrument since the last survey was conducted on 9/23/2021. 3. An interview with testing personnel #1 (TP#1) at approximately 10:45 AM on November 15, 2023, confirmed the laboratory failed to write a procedure for, or document and perform calibration verification for the Chem 8+ panel on the Abbott iStat instrument since the last survey was performed on 9/23/2021.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

	This STANDARD is not met as evidenced by: Based on a records review, a review of the laboratory's policies and procedures manual, and an interview with testing personnel #1 (TP #1), the laboratory failed to evaluate, or establish a policy or procedure that evaluates at least semi-annually molecular test results obtained using two Cepheid instruments since the last survey was performed on 9/23/2021. The laboratory conducts a total of approximately 2,689 microbiology tests annually. Findings include: 1. Based on a records review, the laboratory failed to evaluate at least semi-annually SARS CoV-2/Flu A&B/RSV test results obtained using two Cepheid instruments since the last survey was performed on 9/23/2021. 2. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to establish a policy or procedure that evaluates at least semi-annually SARS CoV-2/Flu A&B/RSV test results obtained using two Cepheid instruments since the last survey was performed on 9/23/2021. 3. Based on an interview with testing personnel #1 (TP #1), at approximately 11:20 AM, on November 15, 2023, confirmed that the laboratory failed to evaluate, or establish a policy or procedure that evaluates SARS CoV-2/Flu A&B/RSV results at least semi-annually since the last survey was performed on 9/23/2021.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a records review, and an interview with the practice manager (not on CMS-209), the laboratory failed to include reference intervals, or "normal" values on their patient laboratory test reports for the specialties of microbiology, chemistry, and hematology since the last survey was conducted on 9/23/2021. The laboratory performs approximately 2,689 microbiology, 1,000 chemistry, and 1,000 hematology tests annually. Findings include: 1. Based on a records review, the laboratory failed to include reference intervals, or "normal" values on their patient laboratory reports since the last survey was conducted on 9/23/2021. 2. Based on an interview with the practice manager (not on CMS-209), at approximately 11:45 AM, on November 15, 2023, confirmed that the laboratory failed to include reference intervals, or "normal" values on their patient laboratory reports since the last survey was conducted on 9/23 /2021.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures manual, and an interview with testing personnel #1 (TP #1), the laboratory failed to establish a policy and procedure for how to document, and notify the ordering provider when a

	laboratory test result indicates an imminently life threating condition, or panic values since the last survey was conducted on 9/23/2021. The laboratory performs approximately 2,689 microbiology, 1,000 chemistry, and 1,000 hematology tests annually. Findings include: 1. Based on a review of the laboratory's policies and procedures manual, the laboratory failed to establish a policy and procedure for how to document, and notify the ordering provider when a laboratory test result indicates an imminently life threating condition, or panic values since the last survey was conducted on 9/23/2021. 2. An interview with testing personnel #1 (TP #1), at approximately 10:15 AM, on November 15, 2023, confirmed the laboratory failed to establish a policy and procedure for how to document, and notify the ordering provider when a laboratory test result indicates an imminently life threating condition, or panic values since the last survey was conducted on 9/23/2021.