Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D2108161	10/11/2022
Name of Provider or Supplier	**Street Address, City, State**	
Urgent Care - Lakewood	12105 W Alameda Pkwy, Ste 100, Lakewood, 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	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on a routine desk review of the CMS-155 report for Proficiency Testing (PT) performance and email communications with the laboratory director of operations, the laboratory failed to achieve satisfactory performance scores for the American Proficiency Institute (API) PT for Cell I.D or WBC Diff testing using the Medonic M-Series instrument for three out of four PT events in 2021 and 2022 (events 3 of 2021 and events 1 and 2 of 2022). See D2130.
D2130	HEMATOLOGY CFR(s): 493.851(f)

	Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a routine desk review of the CMS-155 report for Proficiency Testing (PT) performance and email communications with the laboratory director of operations, the laboratory failed to achieve a score of at least 80% for the American Proficiency Institute (API) PT for Cell I.D. or WBC Diff testing using the Medonic M-Series instrument for events 3 of 2021 and events 1 and 2 of 2022. Findings: 1. A review of the CMS-155 Individual Laboratory Profile on 10/11/2022, at 12:45 pm, revealed the API PT for Cell I.D. or WBC Diff testing scores for 2021 event 3 was 67%, for 2022 event 1 was 73% and event 2 was 0%. 2. Email received from the laboratory director of operations on 10/13/2022, at 11:32 am, confirmed three consecutive unsuccessful PT scores for Cell I.D. or WBC Diff testing due to instrument errors and failure to submit PT results before the deadline.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a routine desk review of the CMS-155 report for Proficiency Testing (PT) performance and email communications with the laboratory director of operations, the laboratory director failed to provide overall management of the laboratory by failing to ensure accurate instrument operation and timely submission of proficiency testing results for Cell I.D. or WBC Diff. See D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a routine desk review of the CMS-155 report for Proficiency Testing (PT) performance and email communications with the laboratory director of operations, the laboratory director failed to provide overall management of the laboratory by failing to ensure accurate instrument operation and timely submission of proficiency testing results for Cell I.D. or WBC Diff. Findings: 1. A review of the CMS-155 Individual Laboratory Profile on 10/11/2022, at 12:45 pm, revealed the API PT for Cell I.D. or WBC Diff testing scores for 2021 event 3 was 67%, for 2022 event 1 was 73% and event 2 was 0%. 2. Email received from the laboratory director of operations on 10/13

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