

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0256801	(X3) Date Survey Completed 12/11/2023
Name of Provider or Supplier Harbin Clinic, Llc - Main Office	Street Address, City, State 101 Redmond Road, Rome, GA	
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
D0000	A proficiency testing desk review was completed on December 11, 2023. At the time of the review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following condition level deficiencies were cited: D2016 - 42 C.F.R. 493.803 Successful participation [proficiency testing] D6000 - 493.1403 Laboratory Director, Moderate Complexity
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 review of the Centers for Medicare and Medicaid (CMS) 155 Report and review of the American Proficiency Institute (API) proficiency testing reports, the

	laboratory failed to successfully participate in 2 out of 3 proficiency testing events resulting in the initial unsuccessful participation in Blood Urea Nitrogen (BUN). Refer to D 2096
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the CMS 155 report and review of API PT reports, the laboratory failed to demonstrate satisfactory performance in 2 of 3 testing events for BUN, resulting in the initial unsuccessful participation for BUN. Findings: 1. Desk review of CMS 155 reports disclosed the laboratory failed BUN with the following scores: 2023 event 1 = 40% 2023 event 3 = 60% 2. Desk review of the laboratory's proficiency testing reports from API confirmed the laboratory failed the aforementioned analyte.
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 review of the CMS 155 report and review of API reports, the laboratory director failed to provide overall management and direction for successful participation in PT. The laboratory director failed to ensure PT samples were tested as required. Refer to D 6016
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 review of the CMS 155 Report and the API PT evaluation reports, the laboratory director failed to ensure successful PT participation. Refer to D 2096