Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	18D0664118	10/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Grace Community Health Center, Inc Dba	57 Summit Drive, Corbin, KY	

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	Based on desk review of proficiency testing (PT) from 2019 through 2022 the laboratory failed to meet the following conditions resulting in non - initial PT performance: D2016 - SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) D6000 - MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403
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 CMS database proficiency report (155D) and American Proficiency Institute (API) performance evaluation from 2019 through 2022 the laboratory failed to successfully participate in four of nine testing events resulting in

	non-initial satisfactory participation for the specialty of Hematology for cell identification (Cell ID). (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 record review of CMS 155D and API performance evaluation for 2019 through 2022, the laboratory failed to attain satisfactory testing scores in four out of nine testing events resulting in non - initial unsuccessful performance for the analyte of Cell ID in 2019 Event3, 2020 Event 1, and 2022 Events 1 and 2. Findings: 1) A review of 155D showed the following results for Cell ID: 2019 Event 3, 0%, 2020 Event 1, 20%, 2022 Event 1,0% 2022 Event 2, 0% 2) A review of API showed the following results for Cell ID: 2019 Event 3, 0%, 2020 Event 1, 20% 2022 Event 1, 0%, 2022 Event 2, 0%
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 CMS 155D and API performance evaluation for 2022 the laboratory director failed to provide overall management and direction to the laboratory for successful participation in proficiency testing. (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 record review of CMS 155D and API performance evaluation from 2019 through 2022 the laboratory director failed ensure successful participation in an HHS approved proficiency testing program. (See D2130)