

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0675381	(X3) Date Survey Completed 03/23/2023
Name of Provider or Supplier Pittsburg Hospital, Llc	Street Address, City, State 2701 Us Hwy 271 North, Pittsburg, TX	
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 survey performed on March 23, 2023, the laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 C.F.R. 493.803 Condition: Successful participation D6076 - 42 C.F.R. 493.1441 Condition: Laboratory Director, high complexity
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on a proficiency desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute proficiency testing records, the laboratory failed to</p>

	<p>successfully participate (100%) in three of four consecutive testing events in 2021 and 2022 for the subspecialty of compatibility resulting in unsuccessful performance. Refer to D2181.</p>
D2181	<p>COMPATIBILITY TESTING CFR(s): 493.863(e)</p> <p>Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, and American Proficiency Institute (API) proficiency testing records from 2021 and 2022, the laboratory failed to achieve a testing event score of satisfactory performance (100%) for three of four consecutive testing events in the subspecialty of compatibility testing. Findings include: 1. A review of the CASPER Report 155 listed the following scores for the API PT Program for compatibility testing: 2021 Event 3: 80% 2022 Event 1: 60% 2022 Event 3: 60% 2. A desk review of the American Proficiency Institute (API) proficiency testing records from 2021 and 2022 confirmed that the laboratory received unsatisfactory consecutive scores for the subspecialty of compatibility testing in 2021 event 3, and 2022 events 1 and 3.</p>
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a proficiency desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute (API) proficiency testing records, the laboratory director failed to ensure successful participation in an HHS-approved proficiency testing program in the subspecialty of compatibility testing. Refer to D6089.</p>
D6089	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile and American Proficiency Institute (API) proficiency testing records, the laboratory</p>

director failed to ensure successful participation in an HHS-approved proficiency testing program in the subspecialty of compatibility testing for three of four consecutive events from 2021 and 2022. Refer to D2181.