

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0382741	(X3) Date Survey Completed 08/31/2021
Name of Provider or Supplier Unitypoint Health-Grinnell Regional Medical Center	Street Address, City, State 210 Fourth Avenue, Grinnell, IA	
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
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on lack of quality control records, review of patient test reports, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 08/31/2021, the laboratory failed to document the Hematoxylin and Eosin stain quality each day of patient testing for one patient (patient identifier A) having fine needle aspirate (FNA) adequacy testing performed on 03/09/2021. The findings include: 1. Patient identifier A had an FNA performed on 03/09/2021. 2. At the time of the survey, the laboratory did not have Hematoxylin and Eosin stain quality records for the FNA testing performed on 03/09/2021. THIS IS A REPEAT DEFICIENCY CITE ON 05/24/2017.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for</p>

acceptability.

This STANDARD is not met as evidenced by:

Based on review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, Form-116, patient test reports and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:00 pm on 08/31/2021, the laboratory failed to indicate the name and address of the laboratory performing fine needle aspirate (FNA) adequacy testing for one out of one patient (patient identifier A) tested in March 2021. The findings include: 1. The CLIA Application for Certification, Form-116 identified the name and address of the testing facility as: UnityPoint Health- Grinnell Regional Medical Center 210 4th Avenue Grinnell, Iowa 50112 2. Patient identifier A had a FNA performed at this location on 03/09/2021. 3. At the time of the survey, personnel identifier #2 confirmed that the test report for patient identifier A did not include the name and address of the laboratory that performed the FNA testing.