

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0400282	(X3) Date Survey Completed 01/06/2022
Name of Provider or Supplier Fairview Ridges Hospital Laboratory	Street Address, City, State 201 E Nicollet Blvd, Burnsville, MN	
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
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: . Based on document review, direct interview and email communications with laboratory personnel, the laboratory failed to follow written policies and procedures that ensure positive identification and optimum integrity for one of one patients reviewed, from the time of collection or receipt of the specimen through completion of testing and reporting of results. Findings are as follows: 1. The laboratory's Patient and Specimen ID Policy - Hospital Inpatient, Outpatient and Ambulatory procedure, provided via email by the Laboratory Manager (LM), indicated that all non test ready labeled specimens must have the full patient name and secondary identifier confirmed from the label of the primary specimen container, prior to transferring specimen and affixing labels to each and every secondary specimen container. 2. Laboratory internal investigative documents (Summary: Narrative for Labeling Event 10.13.2021.doc and Timeline of Events MDH Investigation 137944 KA.xlsx), provided via email by the LM, confirmed that in the case of a serum specimen collected from a patient (Male) at 3:40 p.m., on 10/13/21 at the Fairview Ridges Hospital / Out Patient Lab (FRH/OP), with an physician order for Prostatic Specific Antigen (PSA), these requirements were not followed. 3. Based on interview at 3:00 pm, on 12/16/21 and email communications on 12/21/21 and 1/6/22 with the LM, and review of laboratory documentation, the above findings are confirmed. .</p>