

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1050690	(X3) Date Survey Completed 10/26/2022
Name of Provider or Supplier Northern Tier Research	Street Address, City, State 1302 Madison Ave, Dunmore, PA	
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
D5305	<p>TEST REQUEST CFR(s): 493.1241(c)</p> <p>The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.</p> <p>This STANDARD is not met as evidenced by: Based on the review of test requisitions and interview with the Laboratory Director (LD), the laboratory failed to include the name and address of the authorized person requesting for SARS-CoV-2 RT-qPCR test from 10/06/2020 to 10/26/2022. Findings Included: 1. On the day of survey, a review of 2 of 2 patient test requests revealed that the test requests did not include the name of the authorizing person for CoV-2 RT-qPCR test from 10/06/2020 to 10/26/2022. 2. LD confirmed the above findings on 10/26/2022 at 15:30 PM.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed</p>

following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's record and interview with the Laboratory Director (LD) and Testing Personnel 1 (CMS 209-#1), the laboratory failed to follow the manufacturer's instructions for using the 7 of 7 Chai Bio Open qPCR system from 10/06/2020 to 10/26/2022. Findings Included: 1. According to the Chai open qPCR manual "The Open qPCR instrument is intended for Research Use Only (RUO). Results produced from the instrument are not for use in diagnostic procedures". 2. A review of the laboratory's procedure manual and patient report (2 of 2) revealed that Chai bio-open qPCR system was not being used for research purposes but for clinical diagnostic purposes from 10/06/2020 to 10/26/2022. 3. 1500 covid specimens were tested using the Chai Bio-Open q PCR system from 2021 to 10/26/2022. 4. LD and TP#1 confirm the above findings on 10/26/2022 at 03:17 PM.