

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1050690	(X3) Date Survey Completed 10/06/2020
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of Laboratory procedure manuals and interview with the laboratory director (LD), the laboratory failed to establish a competency assessment policy to assess the competency of 3 of 4 testing personnel (TP) who performed toxicology testing from 2018 to the day of survey. Findings include: 1. On the day of survey, 10/06/2020, the laboratory could not provide a competency assessment policy. 2. In 2019, 3 of 4 TP were not assessed for their annual competency assessment. 2. The LD confirmed the findings above on 10/06/2020 around 09:15 am.</p>
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manuals, interview with the Laboratory director (LD), the LD failed to ensure a quality assessment (QA) programs was established and to assure the quality of laboratory services provided from 2018 to the day of survey. Findings Include: 1. On the date of survey, 10/06/2020, the LD could not provide a QA procedure or documentation of periodic evaluation of the laboratory,</p>

that assess its pre analytical, analytical, and post analytical processes from 05/23/2018 to 10/06/2020. 2. The LD confirmed the finding above on 10/06/2020 around 11:00 am.