



Materials Inspection Record

1. Licensee Name: Labcorp Early Development Laboratories		2. Docket Number(s): 030-38386		3. License Number(s): 21-32816-01	
4. Report Number(s): 2022-001			5. Date(s) of Inspection: April 1, 2022; exit meeting April 6, 2022		
6. Inspector(s): Ryan Craffey		7. Program Code(s): 03620		8. Priority: 5	9. Inspection Guidance Used: IP 87126
10. Licensee Contact Name(s): John Harvey, PhD, CHP - RSO Sarah Krueger, PhD - AU		11. Licensee E-mail Address: john.harvey@westphysics.com sarah.krueger1@labcorp.com		12. Licensee Telephone Number(s): 734-678-7309 734-519-2076	
13. Inspection Type: <input checked="" type="checkbox"/> Routine <input type="checkbox"/> Announced <input type="checkbox"/> Non-Routine <input checked="" type="checkbox"/> Unannounced		14. Locations Inspected: <input type="checkbox"/> Main Office <input checked="" type="checkbox"/> Field Office <input type="checkbox"/> Temporary Job Site <input checked="" type="checkbox"/> Remote		15. Next Inspection Date (MM/DD/YYYY): 04/01/2027 <input checked="" type="checkbox"/> Normal <input type="checkbox"/> Extended <input type="checkbox"/> Reduced <input type="checkbox"/> No change	

16. Scope and Observations:

This was a contract research laboratory authorized to use a variety of isotopes for research and development as well as a variety of millicurie quantity sealed sources for instrument calibration at its facility on Technology Drive in Ann Arbor, Michigan. One authorized user oversaw the receipt, handling, and use of material, which has recently included microcurie to millicurie quantities of F-18, Zr-89, Lu-177, and Ac-225 in efficacy and biodistribution studies of promising radiopharmaceuticals for cancer treatment. The licensee retained the services of a certified health physicist to oversee the implementation of the radiation safety program.

The inspector toured the authorized location of use in Ann Arbor. Restricted areas were properly posted, and all licensed material was adequately secured. The inspector was unable to observe the conduct of licensed activities, as none were scheduled or in progress during the week of the inspection. Instead, the inspector observed demonstrations of hazardous material package receipt, instrument quality control, material handling and use, decay-in-storage waste handling, and area surveys. The inspector also confirmed that the licensee's inventory of sealed sources was fully accounted for. The authorized user was knowledgeable of radiation protection principles and regulatory requirements, and had adequate ALARA measures, all required personnel dosimetry, and calibrated and operable radiation detection instruments available for the continued safe use of licensed material.

The inspector reviewed a selection of records while on-site, including package receipt and area surveys, decay-in-storage waste handling records, personnel dosimetry reports, an incident report from 2021 for minor contamination on a survey instrument, and health physics audits including instrument calibration records as well as sealed source inventories, leak tests, and transfer records.

Following the on-site inspection, the inspector met with the authorized user remotely to review the content and conduct of radiation safety training for employees, including annual radiation safety awareness training for all staff, task-specific, isotope-specific, and other just-in-time training for employees assisting the AU with studies, hands-on training for husbandry staff, and current hazmat training for the AU.

No violations of NRC requirements were identified as a result of this inspection. The inspector held an exit meeting with the licensee following the conclusion of the remote review on April 6, 2022.