DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 Tel: 313-393-8100 Industry Information: www.fda.gov/oc/industry	October 20-24, 2025
	FEI NUMBER 1000140135

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Tanise R. Shattock-Gordon, PhD, Vice President, Analytical Services

FIRM NAME	STREET ADDRESS
Inotiv, Inc	2701 Kent Ave.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
West Lafayette, IN 47906	Biopharmaceutics Analytical Facility & Nonclinical Laboratory

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

The following observation pertain to studies # (b)(4) (for (b)(4)) and # (b)(4) (for (b)(4)):

1. During the validation of insulin aspart in human serum (validation report #1000-2403020), the effect of lipemia for selectivity and matrix effect experiments was not evaluated. Specifically, the firm used plasma matrix to study the lipemia effect for selectivity and matrix effect in serum.

2. Whole blood stability of insulin aspart was not assessed during method validation (validation report #1000-2403020). Specifically, short term stability testing was conducted in plasma.

3. Source records for method validation experiments of long-term stability (validation report #1000-091480-2), dilution integrity, stability in matrix and ion suppression (validation report #1000-091480-1), do not document that lithium heparinized human lysed whole blood was utilized as the matrix. The study samples from study (b)(4) utilized lithium heparinized human lysed whole blood.

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Sripal Reddy Mada, Senior Pharmacologist Barbara D. Wright, Senior Advisor	10/24/2025