

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139		DATE(S) OF INSPECTION 11/20/2024-11/25/2024* FEINUMBER 3005620323	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Matthew Arthur Will, Medical Director			
FIRM NAME Midwest Fertility Specialists		STREET ADDRESS 12188a N Meridian St Ste 250	
CITY, STATE, ZIP CODE, COUNTRY Carmel, IN 46032-4426		TYPE ESTABLISHMENT INSPECTED Reproductive Establishment	
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.			
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 Donors were not screened by a review of relevant medical records for risk factors and clinical evidence of communicable disease agents and diseases. Specifically, Your firm has failed to adequately screen directed semen donors based on your donor screening interview titled "Donor Medical History Interview Form" with no version number or implementation date. This questionnaire failed to screen for risk factors for relevant communicable disease agents and diseases (RCDADs) pertaining to Hepatitis B, Hepatitis C, Syphilis, West Nile Virus (WNV), Creutzfeldt-Jakob Disease (CJD) and variant CJD. In addition, your firm failed to adequately screen based on your physical exam titled "Donor Physical Assessment Form" with no version or implementation date, which does not list corneal scarring consistent with vaccinia keratitis as a physical assessment. This incomplete screening and physical exam affect (b)(4) directed semen donors from (b)(4) through 8/29/2023. Currently there are (b)(4) fertilized tissues that are stored, and (b)(4) have been transferred into recipients since (b)(4).			
OBSERVATION 2 You did not establish and maintain procedures for screening of HCT/P donors. Specifically,			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Lesley Mae P Lutao, Investigator Lesley Mae P Lutao Investigator Signed By: Lesley Mae P. Lutao Date Signed: 11-25-2024 15:17:18 	
		DATE ISSUED 11/25/2024	

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139		DATE(S) OF INSPECTION 11/20/2024-11/25/2024*	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Matthew Arthur Will, Medical Director		FEI NUMBER 3005620323	
FIRM NAME Midwest Fertility Specialists	STREET ADDRESS 12188a N Meridian St Ste 250		
CITY, STATE, ZIP CODE, COUNTRY Carmel, IN 46032-4426	TYPE ESTABLISHMENT INSPECTED Reproductive Establishment		
Your standard operating procedure titled "Human Cells, Tissues, and Cellular and Tissue Based Products (HCT/Ps) Midwest Fertility Specialists Procedure Manual" version 1.00, under section IV: Donor Eligibility in Donor Screening, for CJD or vCJD infection, receiving any transfusion of blood or blood components in France between 1980 and the present is not included. See OBSERVATION 1 for examples.			
*DATES OF INSPECTION 11/20/2024(Wed), 11/21/2024(Thu), 11/22/2024(Fri), 11/25/2024(Mon)			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Lesley Mae P Lutao, Investigator		DATE ISSUED 11/25/2024
Lesley Mae P Lutao Investigator Signed By: Lesley Mae P. Lutao - S Date Signed: 11-25-2024 15:07:12 X			

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."