

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		DISTRICT ADDRESS Inspection by Sam Chapman and Mark Heintzelman on 4/27 & 4/27/88 1988	
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED		DATE OF INSPECTION	C. F. NUMBER
TO: Dr. John Mitchell		4-26-88 4-27-88	
TITLE OF INDIVIDUAL		TYPE ESTABLISHMENT INSPECTED (i.e. bakery, pharmacy)	
FIRM NAME Michigan Dept of Public Health		Biologics	
STREET ADDRESS 3500 N. LOGAN ST		NAME OF FIRM, BRANCH OR UNIT INSPECTED	
CITY AND STATE LANSING MICHIGAN		STREET ADDRESS OF PREMISES INSPECTED	
CITY AND STATE		CITY AND STATE	
DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:			
+4 QA	1) Harvest bottles for pertussis filtration have no autoclave indicators for sterilization.		
+1 fac	2) Building 16 on left side of entrance to Rullis there was a hole in the wall.		
3 valid	3) Honeywell temperature recorder for pertussis growth incubator located in Room 124 Bld 16 was not calibrated.		
+3 QA	4) Building 16 Room 115 a carboy used for the pooling of pertussis had no autoclave indicator for sterilization.		
+2 SOP	5) there is no written testing procedure for assessing stability characteristics of final biological products.		
+3 valid	6) Validation was not available to document that the glassware washing process removed detergent.		
+3 record	7) No direct physical accountability for packaged undated anthrax vaccine which was stored alongside of packaged and dated vaccine with the same lot number. Nine hundred and six vials of unfinished vaccine were distributed freely in 3 cardboard boxes with unknown number of vials in each carton. Removal of vials as needed was not indicated.		
	(OVER)		
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Mark D. Heintzelman	EMPLOYEE(S) TITLE Biologist	