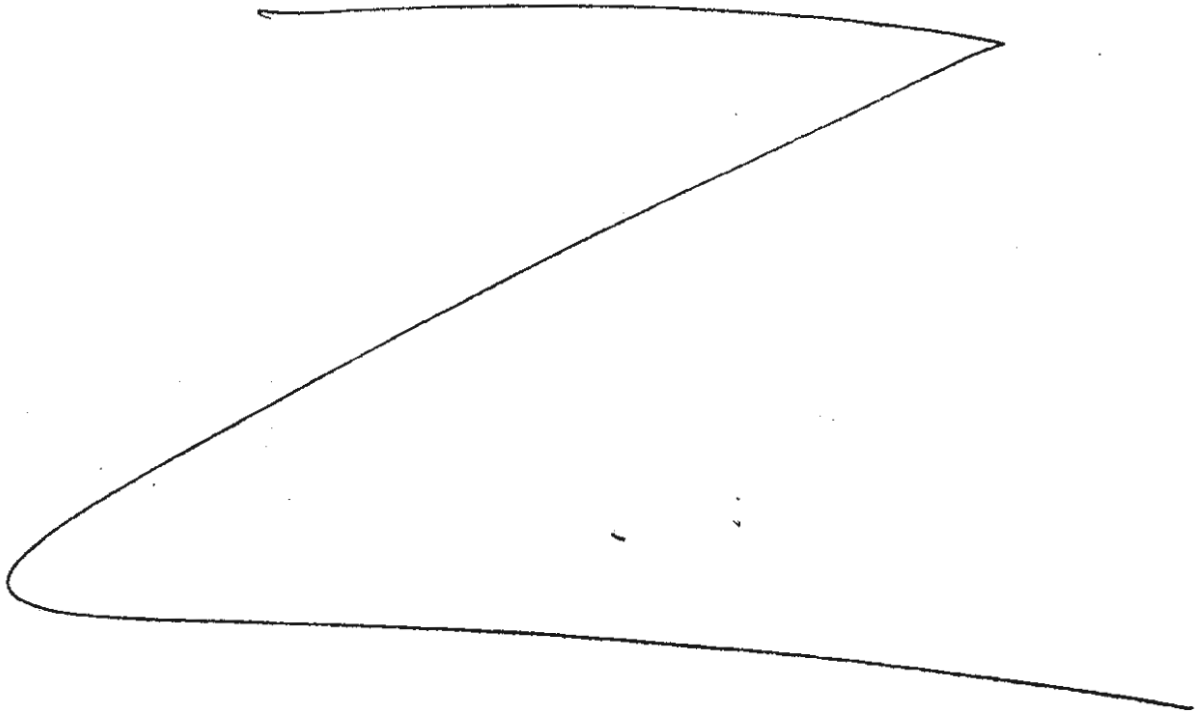


DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION	
FDA 60 8th Street, NE Atlanta, Georgia 30309		10/9/03, 10/10/03, 10/14/03	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED		FEI NUMBER	
TO: Thomas J. Lynch, Vice President, Regulatory Affairs & Quality Assurance		3001451326	
FIRM NAME	STREET ADDRESS		
CryoLife Inc.	1655 Roberts Blvd.		
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED		
Kennesaw, Georgia 30144	Human Tissue Firm		
DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:			

Failure to validate written procedures for prevention of infectious disease contamination during processing. Specifically, the Anti-microbial cocktail which is sometimes referred to as Combo Cocktail Solution has not been validated. The firm has not validated the processing operations/procedures for decontaminating tissue.



SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Leslie W. Gilbert Vincent M. Williams	EMPLOYEE(S) NAME AND TITLE (Print or Type) LESLIE W. GILBERT, Investigator Vincent M. Williams, Supv. Ins.	DATE ISSUED 10/14/03
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