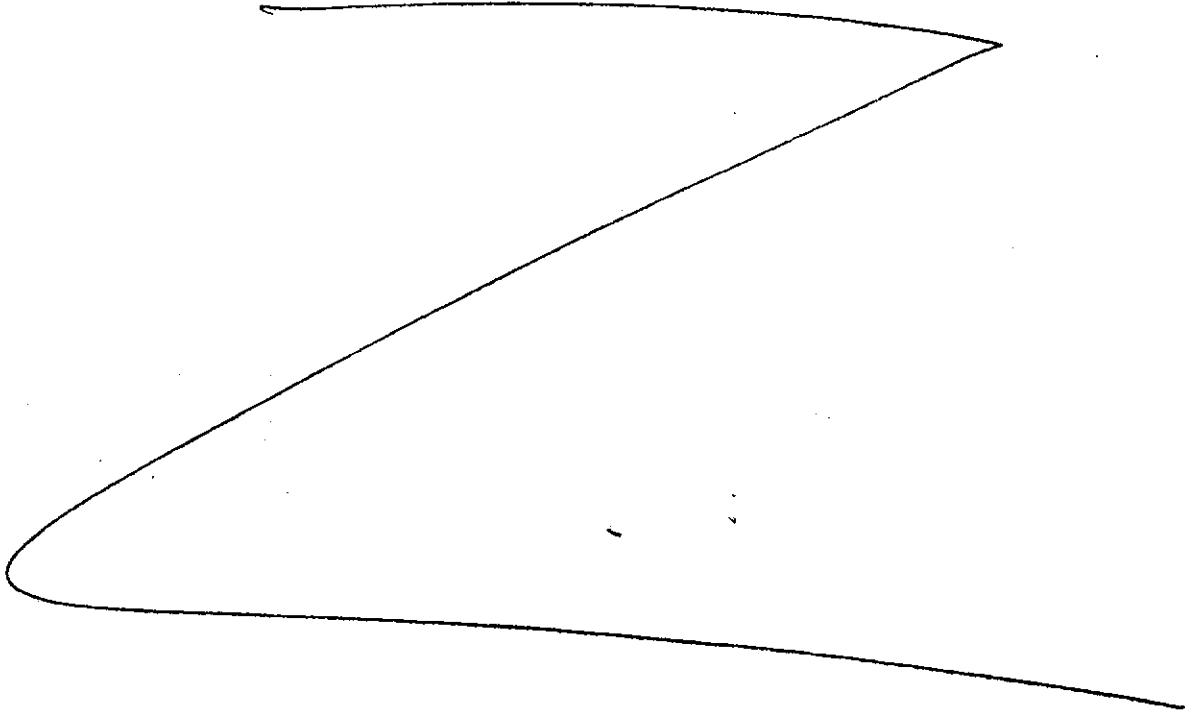


DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA 60 8th Street, NE Atlanta, Georgia 30309		DATE(S) OF INSPECTION 10/9/03, 10/10/03, 10/14/03
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Thomas J. Lynch, Vice President, Regulatory Affairs & Quality Assurance		FEI NUMBER 3001451326
FIRM NAME CryoLife Inc.	STREET ADDRESS 1655 Roberts Blvd.	
CITY, STATE AND ZIP CODE Kennesaw, Georgia 30144	TYPE OF ESTABLISHMENT INSPECTED 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. ...	EMPLOYEE(S) NAME AND TITLE (Print or Type) LESLIE W. GILBERT, Investigator Vincent M. ...	DATE ISSUED 10/14/03
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