



Microbiology Out of Specification (OOS) Investigation and Report Form

(Ref. MICLAB 110)

Phase 1

Out of Specification Result
(Action Level Excursions)

Out of Limits Result
(Alert Limit Excursions)

SECTION A – Product or Sample Details

Form Initiated by:		Unique Identifier	
Product Description		DR Number	
Batch Production Number (BPN)		Product Code	
Original Test Result		Limits/ Specification	
Micro Manager Notified	Yes <input type="checkbox"/> No <input type="checkbox"/>	By who?	Initial and Date

SECTION B – Evaluation of Laboratory Testing

Test Type	(tick)	SOP Reference	Control Method reference (if applicable)
Non-Sterile Testing	<input type="checkbox"/>	MICLAB 075	
Water	<input type="checkbox"/>	MICLAB 055	
Sterility Testing	<input type="checkbox"/>	MICLAB 060	
Endotoxin	<input type="checkbox"/>	MICLAB 085	
	<input type="checkbox"/>	MICLAB 080	
Other	<input type="checkbox"/>		
Name of Technician who performed the test			Training records complete Yes <input type="checkbox"/> No <input type="checkbox"/>
Date Sampled			Date Test performed
Was test conducted in accordance with SOP & Control method	Yes <input type="checkbox"/> No <input type="checkbox"/>	If No, comment:	
Media/Reagents Used	Lot Number	Expiry Date	Passed QC Checks
			Yes <input type="checkbox"/> No <input type="checkbox"/>
			Yes <input type="checkbox"/> No <input type="checkbox"/>
			Yes <input type="checkbox"/> No <input type="checkbox"/>
			Yes <input type="checkbox"/> No <input type="checkbox"/>
			Yes <input type="checkbox"/> No <input type="checkbox"/>
			Yes <input type="checkbox"/> No <input type="checkbox"/>



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PART B – Evaluation of Laboratory Testing (continued)

Equipment Used	Calibration Due Date	Temperature Trends in range	
		Yes <input type="checkbox"/> No <input type="checkbox"/>	N/A <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>	N/A <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>	N/A <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>	N/A <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>	N/A <input type="checkbox"/>
		Yes <input type="checkbox"/> No <input type="checkbox"/>	N/A <input type="checkbox"/>
Test result record Attached?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comments:	
Are Calculations Verified and correct?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comments:	
Negative Controls passed?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comments:	
Other tests from same test session within limits?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comments:	
Other Sources of Error? Technician observations during testing?	Yes <input type="checkbox"/> No <input type="checkbox"/>	Comments:	
Brief Description of the Investigation Findings to date.			
Is initial Result Valid? (ie has root cause been identified)	Yes <input type="checkbox"/> No <input type="checkbox"/>	If No, is re-testing required	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
		If Yes, is confirmatory or investigational testing required?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
		If Yes, DR raised & recorded in Section A	Yes <input type="checkbox"/> Initials & Date

Note : If any of the above questions were answered NO, an evaluation of the validity of the test needs to be conducted by the Micro Manager.

	Print	Sign	Date
Approved By: Micro Manager			

NOTE: Refer to MICLAB 110 for appropriate Retest Procedures.



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Phase 2

PART C – Retest Protocol

Retest testing of Original Sample(s)	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
Confirmatory Testing of Original or retention Sample(s) for investigational purposes	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
Retest of Retain samples	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
Retest of Both Original and retain sample	Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>
Number of Replicates to be Tested			
Test Method			
Limits for Retest			
Retesting Conducted by	Print	Sign and Date	
Please document the purpose of additional testing as detailed above.			
Retest Protocol Approved By: Micro Manager	Print	Sign	Date

PART C – Retest Protocol (continued) - Retest Results

Document result of Retesting in this section. Please attach hardcopy of raw data.			
Approved By: Micro Manager	Print	Sign	Date