

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

**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
<b>Approved By: Micro Manager</b>			

NOTE: Refer to MICLAB 110 for appropriate Retest Procedures.

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**Phase 2**

***PART C – Retest Protocol***

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

***PART C – Retest Protocol (continued) - Retest Results***

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