

 <b>GMPPENS.COM™</b> cGMP Compliant Indelible Ink™	Document No.:	SOP-004A-FORM-01	
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Document Title:	Lot Testing and Data Form		

## Order Information

Vendor	
Order Date	
Lot Number	
Purchase Order Number	
Ordered By:	

Performed By: \_\_\_\_\_ Date: \_\_\_\_\_

## Receipt Information

Receipt Date	
Was order complete?	YES / NO
Receipt Quantity	
Lot Number	
Was Package damaged?	YES / NO

Performed By: \_\_\_\_\_ Date: \_\_\_\_\_

## Sampling

Take the following Samples:

Sample	Quantity	Quantity taken
Testing	40 for orders $\leq 4,000$ pens 60 for orders from 4,001 to 10,000 pens 80 for orders $\geq 10,001$ pens	
Retention	10 pens	

Performed By: \_\_\_\_\_ Date: \_\_\_\_\_

Reviewed By: \_\_\_\_\_ Date: \_\_\_\_\_

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## Labeling

Label the materials for Quarantine per SOP-003.

Performed By: \_\_\_\_\_ Date: \_\_\_\_\_

## Quality Test 1: Labeling

Inspect all sampled pens per SOP-004 and record the results below:

Test	# Fail
Clarity of Imprint	
Accuracy of Imprint	
70% Isopropyl Alcohol Wipe	

Performed By: \_\_\_\_\_ Date: \_\_\_\_\_

## Quality Test 2: Retraction

Inspect all sampled pens per SOP-004 and record the results below.

Test	# Fail
Retraction	

Performed By: \_\_\_\_\_ Date: \_\_\_\_\_

Reviewed By: \_\_\_\_\_ Date: \_\_\_\_\_





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## Quality Test 4: Water Indelibility Test

Use the grid below to make a star or an asterisk (★ or ✱) with each test pen, and perform the test per SOP-004.


Performed By: \_\_\_\_\_

Date: \_\_\_\_\_

Reviewed By: \_\_\_\_\_

Date: \_\_\_\_\_



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## Quality Test 5: Steam Indelibility Test

Use the grid below to make a star or an asterisk (★ or ✱) with each test pen, and perform the test per SOP-004.


Performed By: \_\_\_\_\_

Date: \_\_\_\_\_

Reviewed By: \_\_\_\_\_

Date: \_\_\_\_\_

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## Summary

Record the number of defects noted for each test:

Quality Test #	Defect Type (AQL)	Number Defects noted
1: Labeling	Critical 0.1%	
2: Retraction	Cosmetic 4.0%	
3: Ink Delivery	Minor 1.5%	
4: Ink Color	Critical 0.1%	
5: Water Indelibility	Major 0.4%	
6: Steam Indelibility	Major 0.4%	

Record the number of each type of defect on the bottom row and circle the row with the correct sample size.

Sample Size	Maximum Critical Defects	Maximum Major Defects	Maximum Minor Defects	Maximum Cosmetic Defects
40	0	1	1	2
60	0	1	2	4
80	0	2	3	6
Number of Defects:				
Pass/ Fail				

Performed By: \_\_\_\_\_

Date: \_\_\_\_\_

Reviewed By: \_\_\_\_\_

Date: \_\_\_\_\_

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## Lot Disposition

After review, check the appropriate box to either approve or reject this lot. Operations and Quality Assurance must sign and date below.

This lot is:    **Approved**      
                      **Rejected**   

Role	Name	Signature	Date
Operations			
Quality Assurance			

## Labeling

Replace Quarantine Label with (circle one):    **APPROVED**            **REJECTED**

Performed By: \_\_\_\_\_ Date: \_\_\_\_\_

## Certificate of Compliance

Certificate of Compliance (SOP-004-FORM-02) generated per SOP-002:

**YES**      
**NO**    

Certificate Number: \_\_\_\_\_

Performed By: \_\_\_\_\_ Date: \_\_\_\_\_

Reviewed By: \_\_\_\_\_ Date: \_\_\_\_\_