

Package Insert Review Form

Reagent: _____ Manufacturer: _____

Receive Date	Package Insert		Critical Material	
	New Version #	Current Version Number	Lot Number	Expiration Date

Brief description of difference(s) between version:

Is revision to SOP, policy or other process required? (select the appropriate answer below)

- | | |
|-------------------------------------|---|
| <input type="checkbox"/> NO | Perform the following: <ul style="list-style-type: none"> • Attach a copy of the new and previous package insert • Replace current package insert with the new version in the Package Insert Binder • Submit form for supervisor review |
| <input type="checkbox"/> YES | Perform the following: <ul style="list-style-type: none"> • Briefly describe the change(s) need below • Quarantine the lot number with the new package insert • Attach a copy of the new and previous package insert • Submit form for supervisor review |

Changes usually not requiring SOP revisions:

Company Name/Logo
 Fonts
 Bibliography
 Glossary
 Product Codes

Changes that may require SOP revisions:

Intended Use	Interpretation
Storage requirements	Limitations
Precautions	Specific performance characteristics
Stability of the reaction	Sensitivity Specificity
Test procedure	Specimen collection requirements
Quality Control	

Tech ID: _____ **Date:** _____

FOR MANAGER USE ONLY

Brief description of required changes or comments:

Date revision(s) completed:

QARA Review: _____ **Date:** _____