INTRODUCTION

This checklist is used in conjunction with the All Common and Laboratory General Checklists to inspect an immunology laboratory section or department.

Certain requirements are different for waived versus nonwaived tests. Refer to the checklist headings and explanatory text to determine applicability based on test complexity. The current list of tests waived under CLIA may be found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm.

Policy/Procedure icon - The placement of this icon next to a checklist requirement indicates that a written policy or procedure is required to demonstrate compliance with the requirement. The icon is not intended to imply that a separate policy or procedure is required to address individual requirements. A single policy or procedure may cover multiple checklist requirements.

Laboratories not subject to US regulations: *Checklist requirements apply to all laboratories unless a specific disclaimer of exclusion is stated in the checklist. When the phrase "FDA-cleared/approved test (or assay)" is used within the checklist, it also applies to tests approved by an internationally recognized regulatory authority (eg, CE-marking).*

QUALITY MANAGEMENT

CALIBRATION AND STANDARDS

Inspector Instructions:

READ	• Sampling of calibration and AMR policies and procedures • Sampling of calibration/calibration records • Sampling of AMR verification records • Sampling of patient reports and worksheets for verification of results outside of AMR
OBSERVE	• Sampling of calibration materials (labeling, storage, quality)
ASK	• What is your course of action if calibration is unacceptable? • When was the last time you performed a calibration procedure and how did you verify the calibration? • What is your course of action when results fall outside the AMR?
DISCOVER	• Further evaluate the responses, corrective actions, and resolutions for unacceptable calibration, unacceptable calibration verification, and results outside the AMR