

TRAINING UPDATE

Lab Location: GEC, SGMC & WOMC
Department: Mgmt, QA, IT & Tech.
Specialists

Date Distributed: 7/2/2021
Due Date: 8/1/2021

DESCRIPTION OF REVISION

Name of procedure:

Equipment and Process Validation Protocol
AG.F204 / 204A v2

Description of change(s):

Header: added FWMC

Section D: simplified by removing all the spaces for who would perform & approve IQ, OQ & PQ and added explanations plus some examples.

Note - the form is available in both Excel and Word format, only the Word version is attached.

This revised FORM was implemented July 1, 2021

Document your compliance with this training update by taking the quiz in the MTS system.

- Germantown Emergency Center
- Shady Grove Medical Center
- White Oak Medical Center
- Fort Washington Medical Center

EQUIPMENT/PROCESS VALIDATION PROTOCOL

A. Process Title:

Protocol prepared by: _____ Date _____

Protocol approved by: _____ Date _____

B. Purpose of Validation

C. Requirements and specifications

D. Test Plan see SOP *Process and Equipment Validation Protocol* (Definitions and Addendum B)

Installation Qualifications (IQ):

*(Identify steps to ensure equipment is **installed** per manufacturer's requirements)*

Operational Qualification (OQ): *(Identify steps to ensure that the equipment or process **operates as expected** per manufactures specifications. Examples include obtaining correct RPMs, temps and timing.)*

Performance Qualification (PQ): *(Identify steps to ensure that **equipment performs as expected**. Examples include correlating with reference method; passing QC; producing accurate results)*

a. SOPs/Personnel/Equipment/Materials Required

SOPs:

Personnel:

Materials:

b. Test Samples Required

c. Testing Conditions

d. Data Collected

E. Implementation Plan/Change Control

F. Validation Results

G. Conclusions

Validation reviewed by: _____ **Date:** _____

Approved by: _____ **Date:** _____