

Synthetic SOP - Compliant

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Approved by: Dr. QA Manager

Revision History

Version	Date	Change
1.0	2021-11-21	Initial release

Introduction

This protocol describes how to screen commercial antibodies by immunoblot using wildtype (WT) and knockout (KO) cell lysates. Proteins are separated on a polyacrylamide gel and transferred to a nitrocellulose membrane. These membranes are incubated with commercial primary antibodies and then with HRP secondary antibodies. A specific band is detected in the parental cell lysis and should disappear in the KO lysate.

Purpose

Describe the standard procedure for the activity in scope.

Scope

Applicable to laboratory staff performing the described process.

Responsibilities

QA is responsible for review and approval; Authors for drafting; SMEs for review.

Definitions

WT: Wild Type; KO: Knockout; SOP: Standard Operating Procedure.

Procedure

1. Prepare materials
2. Perform steps as per checklist
3. Record outcomes

References

ICH Q7; ISO 13485:2016; 21 CFR Part 11

Approvals

Prepared by: _____ Reviewed by: _____ Approved by: _____