Synthetic SOP - Outdated\_References

Document ID: SOP-004

Version: 1.0

Effective Date: 2010-05-10

Prepared by: Scientist A

# References

ISO 9001:1994

ICH Q7 (2001)

21 CFR Part 11 (1997)

# 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: \_\_\_\_\_\_\_\_\_\_