



Project Number: 3527/5	Title: Traceability for urine measurements with the visual Combur test strips	
Document ID: COM00-0041	Version: 1.0 Date: 05-Feb-2018	Page: 2 of 13

TABLE OF CONTENTS

1 Introduction 3

1.1 Purpose 3

1.2 Scope 3

2 Traceability Chain for pH..... 4

3 Traceability Chain for LEU 5

4 Traceability Chain for NIT..... 6

5 Traceability Chain for PRO..... 7

6 Traceability Chain for GLU..... 8

7 Traceability Chain for KET 9

8 Traceability Chain for UBG 10

9 Traceability Chain for BIL..... 11

10 Traceability Chain for ERY 12

11 Traceability Chain for SG 13

Project Number: 3527/5	Title: Traceability for urine measurements with the visual Combur test strips	
Document ID: COM00-0041	Version: 1.0 Date: 05-Feb-2018	Page: 3 of 13

1 Introduction

1.1 Purpose

The metrological traceability allows to relate each measurement result to a reference through a documented unbroken chain of calibrations. Thereby it ensures comparability in measurement results between different laboratories and instruments worldwide.

1.2 Scope

This document describes the traceability for the Combur 10 Test and Combur 10 Test UX test strips which are the masters for professional use Combur test strips with visual reading. The family concept is described in SOP "F_DO0044_SOP_EN". The full list of all family members belonging to these masters can also be found there.

A concept for traceability for urine measurements is developed for the visual Combur 10 Test and Combur 10 Test UX test strip.

The visual Combur test strips are intended to be used for the semi-quantitative determination of pH (pH), leucocytes (LEU), nitrite (NIT), protein/albumin (PRO), glucose (GLU), ketones (KET), urobilinogen (UBG), bilirubin (BIL), blood/erythrocytes/hemoglobin (ERY), specific gravity (SG) in urine for evaluation by visual reading.

For each of the test pads a traceability chain is given separately.

Project Number: 3527/5	Title: Traceability for urine measurements with the visual Combur test strips	
Document ID: COM00-0041	Version: 1.0 Date: 05-Feb-2018	Page: 4 of 13

2 Traceability Chain for pH

The traceability chain for pH determination on the visual Combur test strips can be displayed as follows:

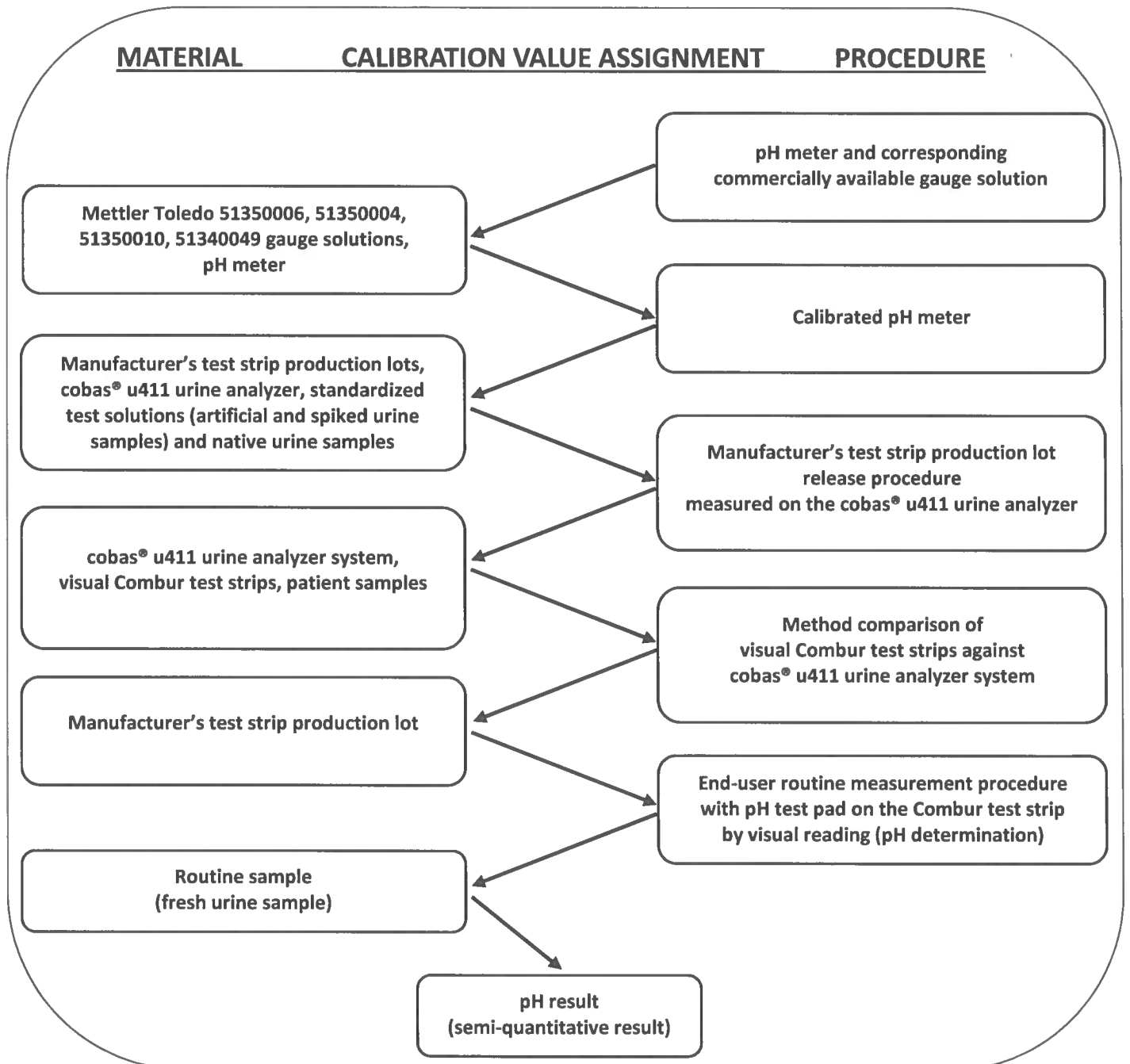


Figure: Traceability chain for the pH determination with the pH test pad on the Combur test strips

Project Number: 3527/5	Title: Traceability for urine measurements with the visual Combur test strips	
Document ID: COM00-0041	Version: 1.0 Date: 05-Feb-2018	Page: 5 of 13

3 Traceability Chain for LEU

The traceability chain for LEU determination on the visual Combur test strips can be displayed as follows:

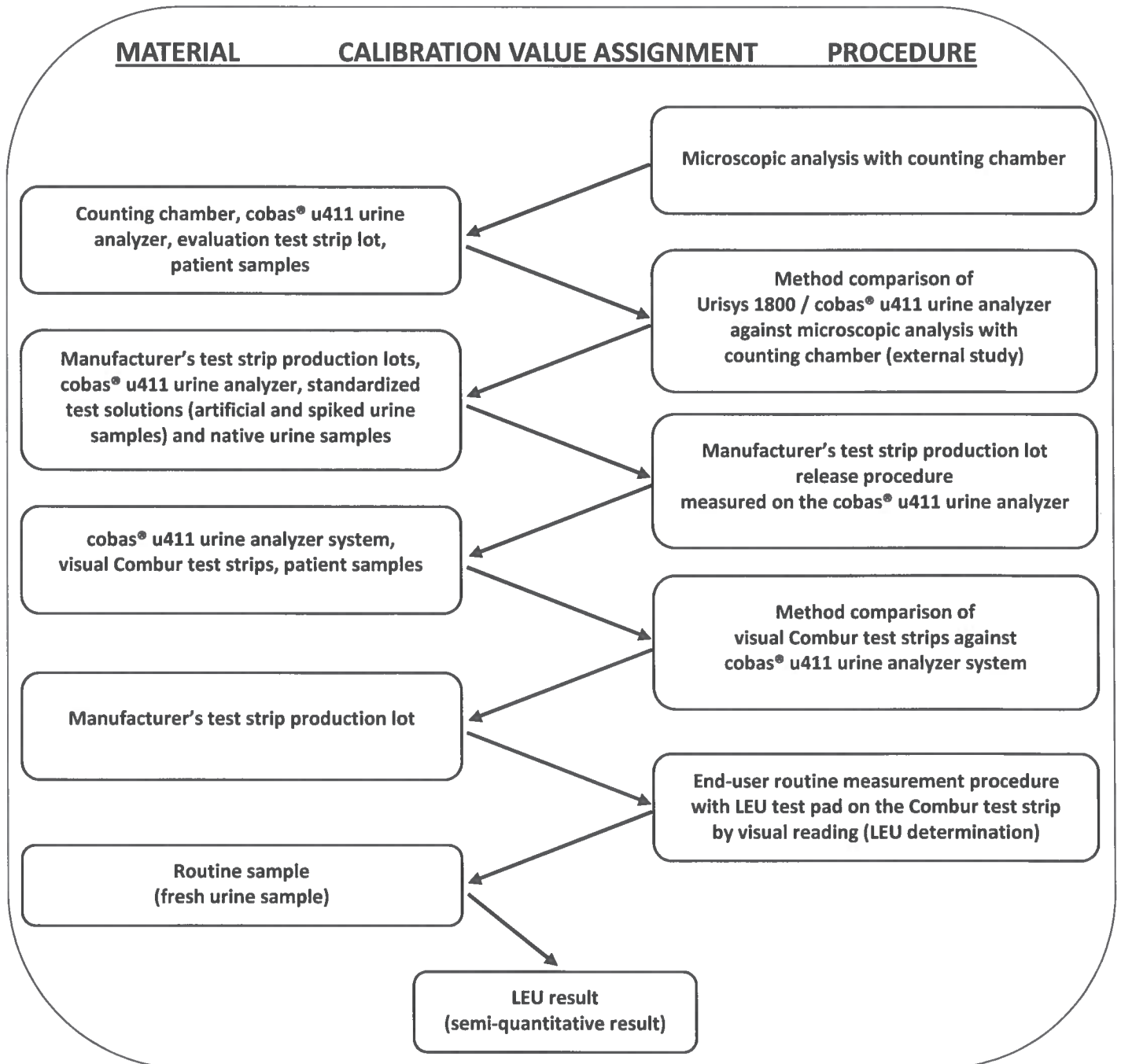


Figure: Traceability chain for the LEU determination with the LEU test pad on the Combur test strips

Project Number: 3527/5	Title: Traceability for urine measurements with the visual Combur test strips	
Document ID: COM00-0041	Version: 1.0 Date: 05-Feb-2018	Page: 6 of 13

4 Traceability Chain for NIT

The traceability chain for NIT determination on the visual Combur test strips can be displayed as follows:

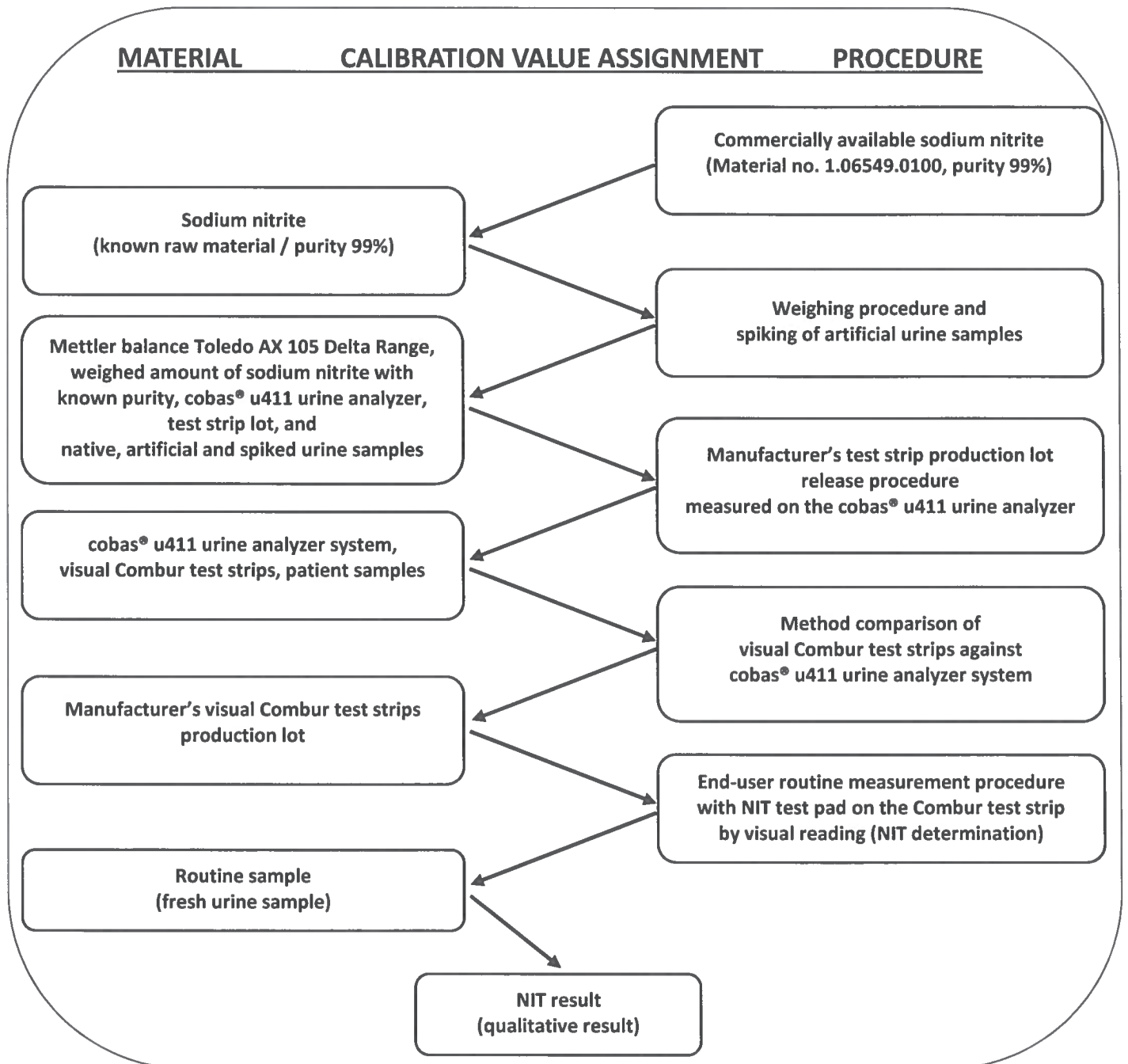


Figure: Traceability chain for the NIT determination with the NIT test pad on the Combur test strips

Project Number: 3527/5	Title: Traceability for urine measurements with the visual Combur test strips	
Document ID: COM00-0041	Version: 1.0 Date: 05-Feb-2018	Page: 7 of 13

5 Traceability Chain for PRO

The traceability chain for PRO determination on the visual Combur test strips can be displayed as follows:

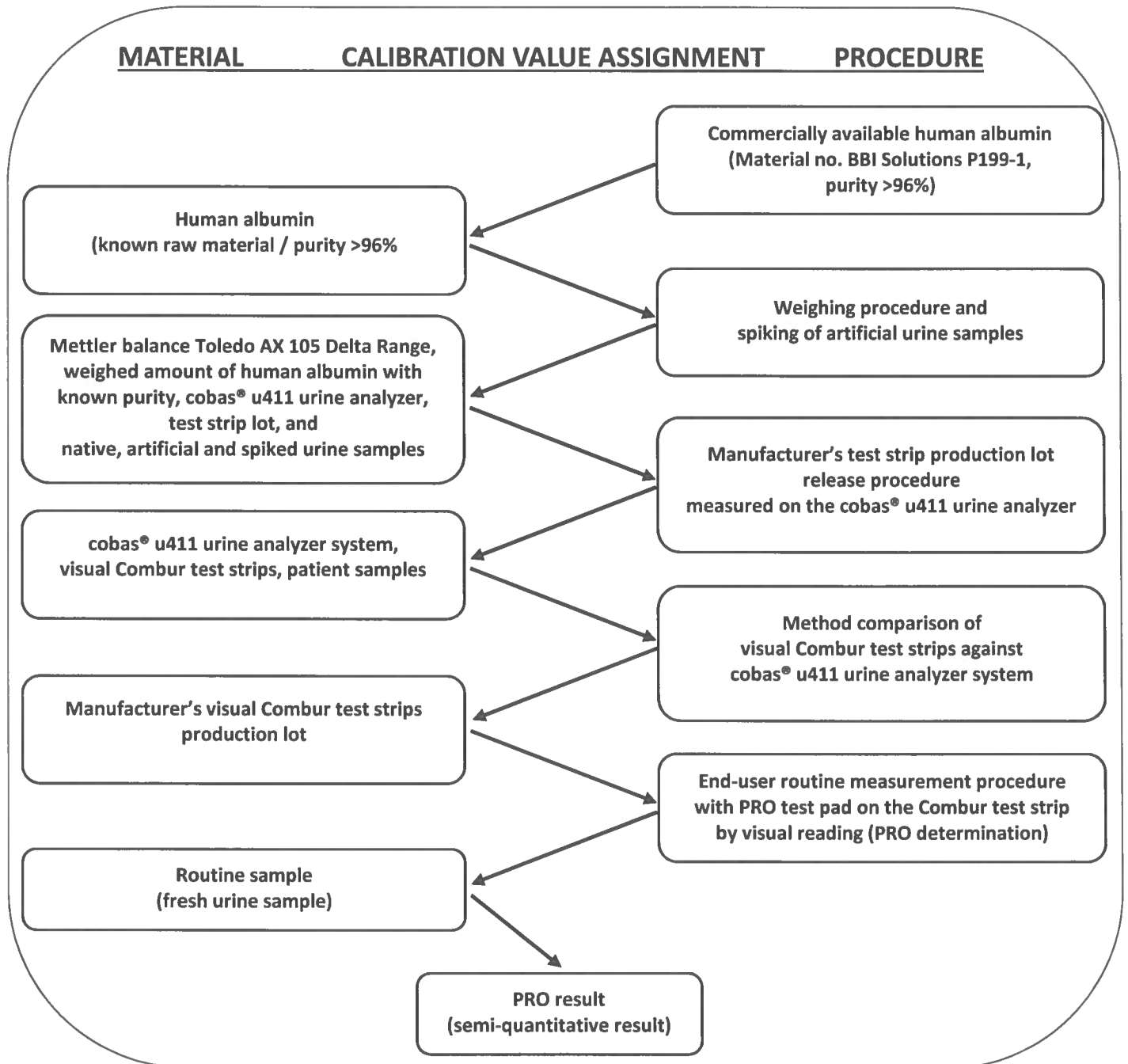


Figure: Traceability chain for the PRO determination with the PRO test pad on the Combur test strips

Project Number: 3527/5	Title: Traceability for urine measurements with the visual Combur test strips	
Document ID: COM00-0041	Version: 1.0 Date: 05-Feb-2018	Page: 8 of 13

6 Traceability Chain for GLU

The traceability chain for GLU determination on the visual Combur test strips can be displayed as follows:

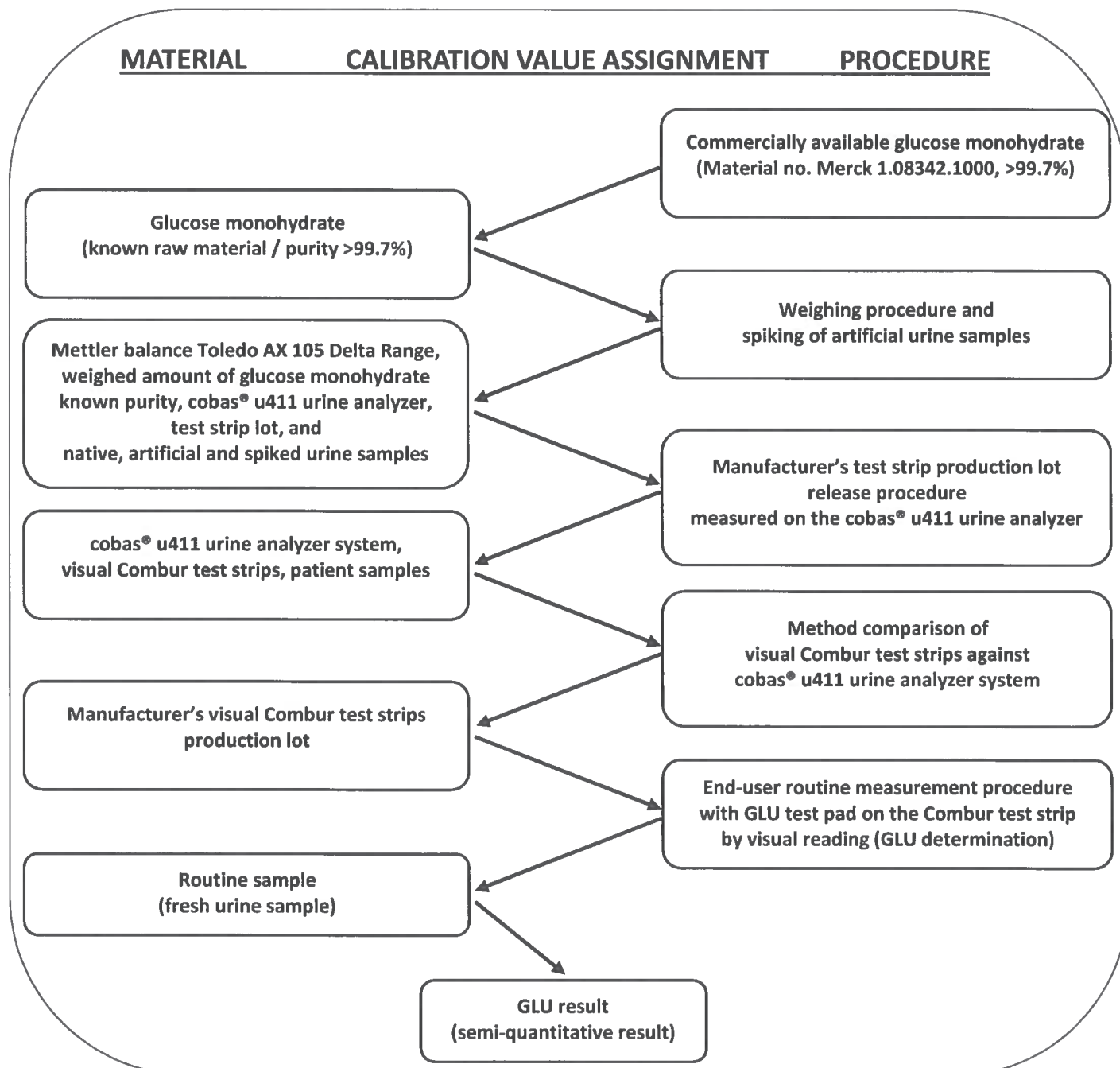


Figure: Traceability chain for the GLU determination with the GLU test pad on the Combur test strips

Project Number: 3527/5	Title: Traceability for urine measurements with the visual Combur test strips	
Document ID: COM00-0041	Version: 1.0 Date: 05-Feb-2018	Page: 9 of 13

7 Traceability Chain for KET

The traceability chain for KET determination on the visual Combur test strips can be displayed as follows:

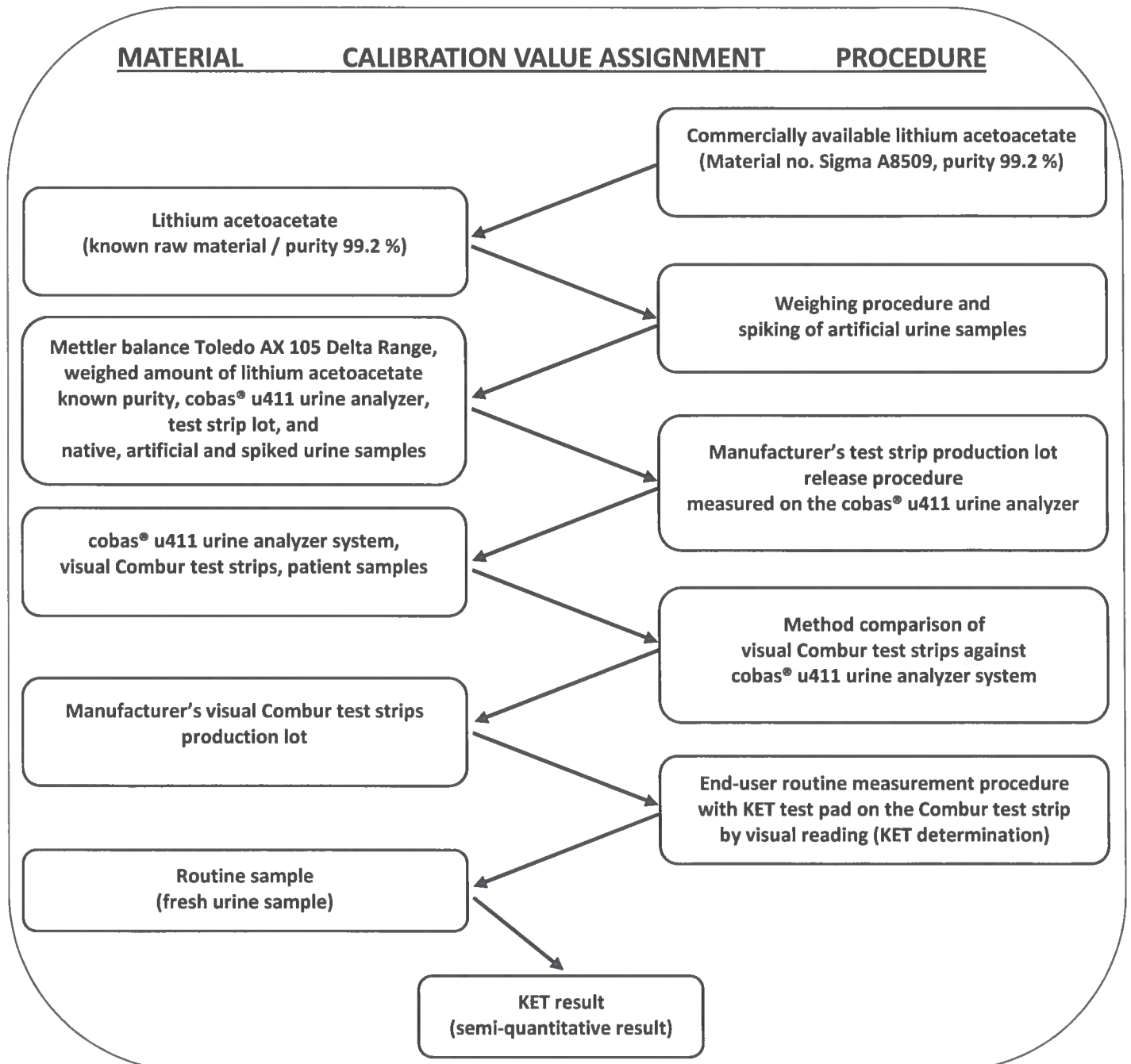


Figure: Traceability chain for the KET determination with the KET test pad on the Combur test strips

Project Number: 3527/5	Title: Traceability for urine measurements with the visual Combur test strips	
Document ID: COM00-0041	Version: 1.0 Date: 05-Feb-2018	Page: 10 of 13

8 Traceability Chain for UBG

The traceability chain for UBG determination on the visual Combur test strips can be displayed as follows:

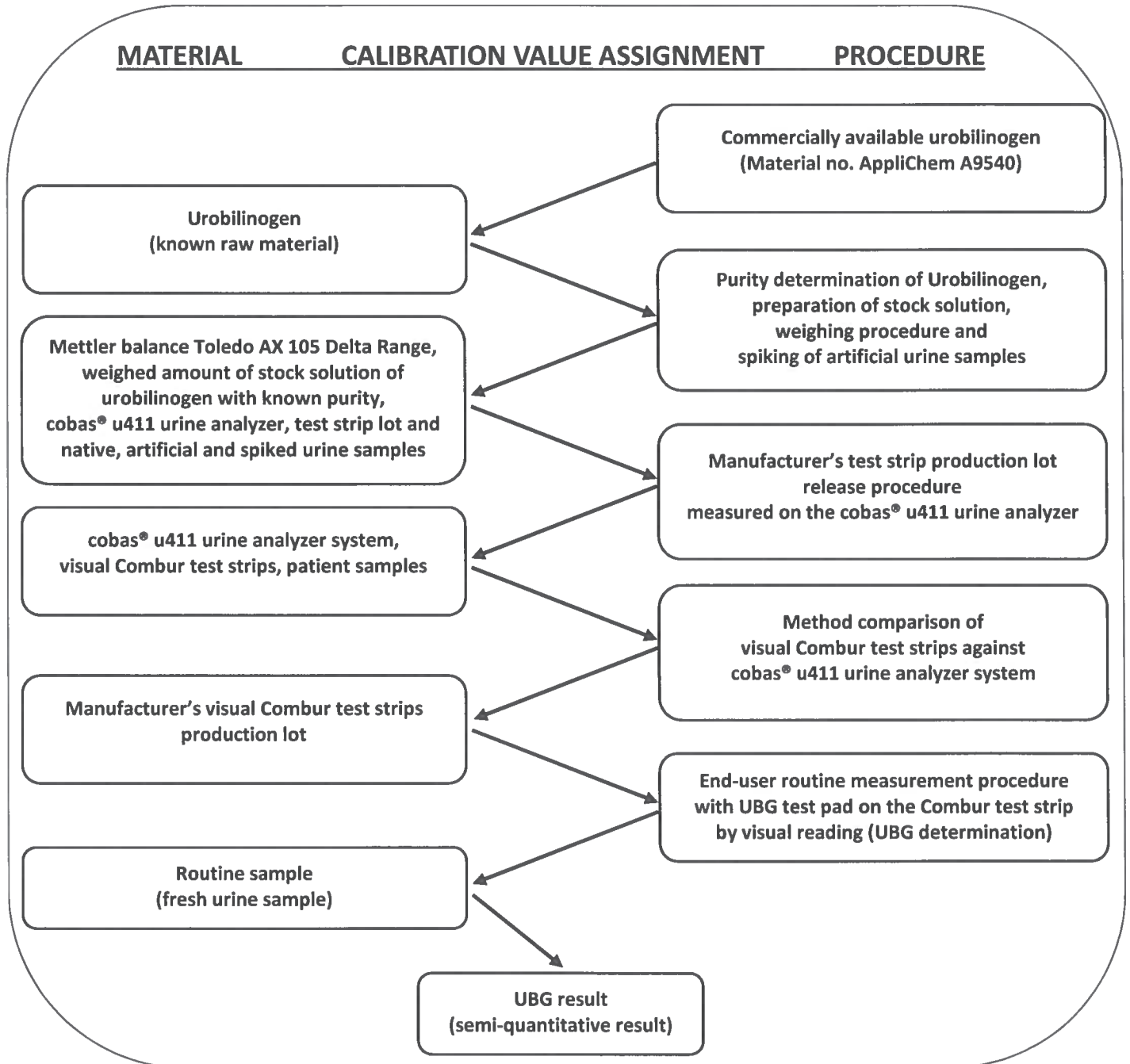


Figure: Traceability chain for the UBG determination with the UBG test pad on the Combur test strips

Project Number: 3527/5	Title: Traceability for urine measurements with the visual Combur test strips	
Document ID: COM00-0041	Version: 1.0 Date: 05-Feb-2018	Page: 11 of 13

9 Traceability Chain for BIL

The traceability chain for BIL determination on the visual Combur test strips can be displayed as follows:

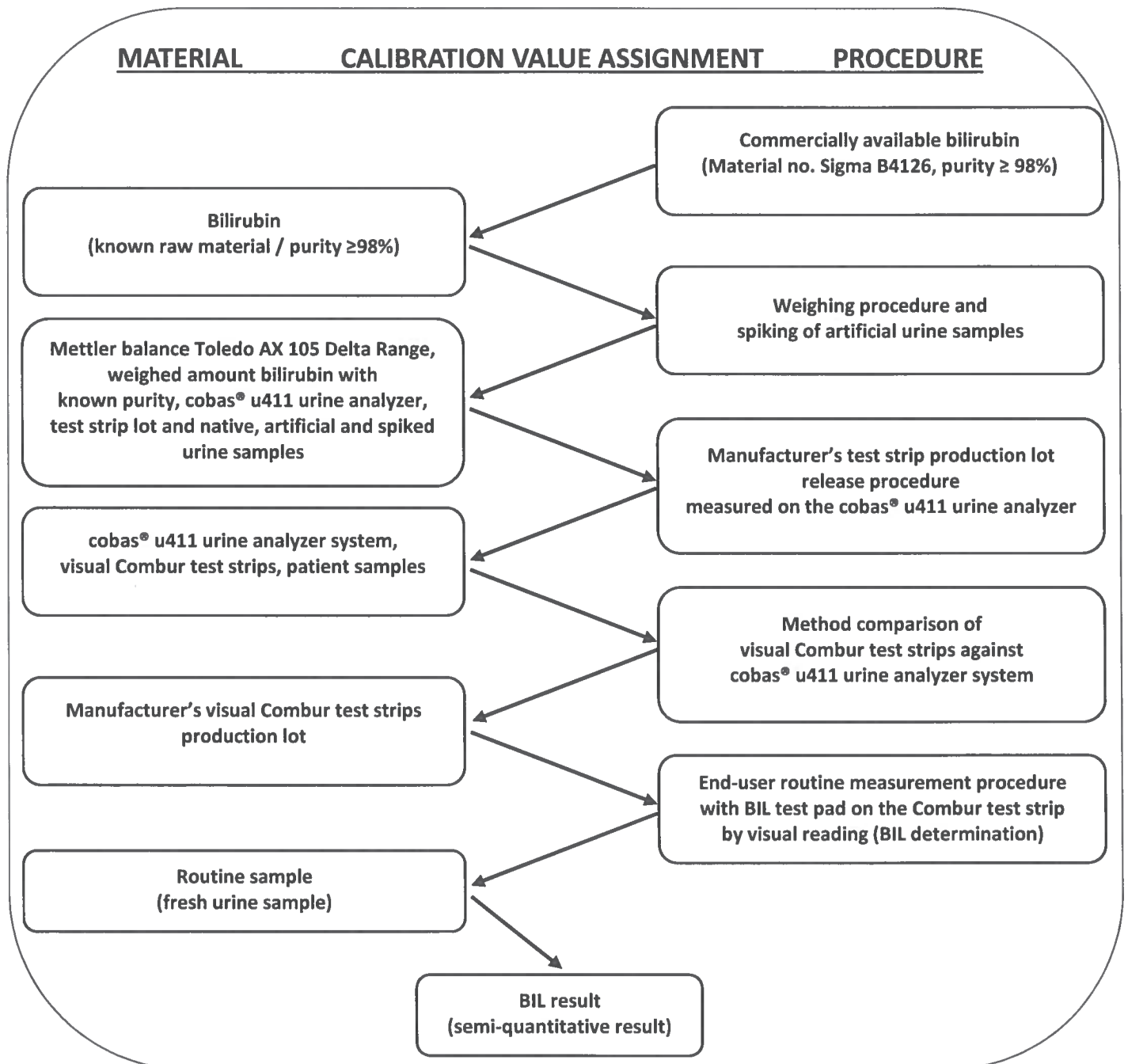


Figure: Traceability chain for the BIL determination with the BIL test pad on the Combur test strips

Project Number: 3527/5	Title: Traceability for urine measurements with the visual Combur test strips	
Document ID: COM00-0041	Version: 1.0 Date: 05-Feb-2018	Page: 12 of 13

10 Traceability Chain for ERY

The traceability chain for ERY determination on the visual Combur test strips can be displayed as follows:

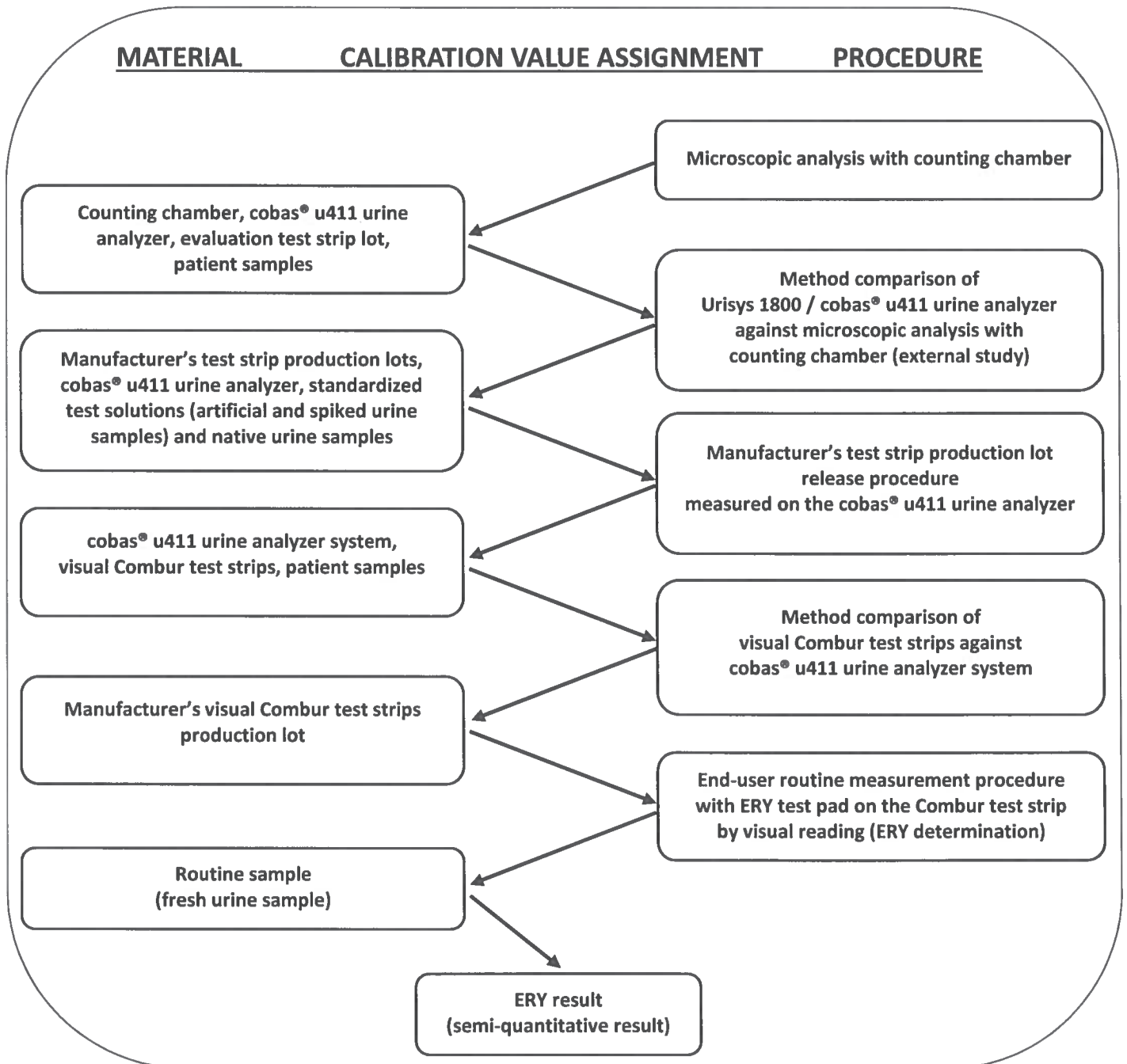


Figure: Traceability chain for the ERY determination with the ERY test pad on the Combur test strips

Project Number: 3527/5	Title: Traceability for urine measurements with the visual Combur test strips	
Document ID: COM00-0041	Version: 1.0 Date: 05-Feb-2018	Page: 13 of 13

11 Traceability Chain for SG

The traceability chain for SG determination on the visual Combur test strips can be displayed as follows:

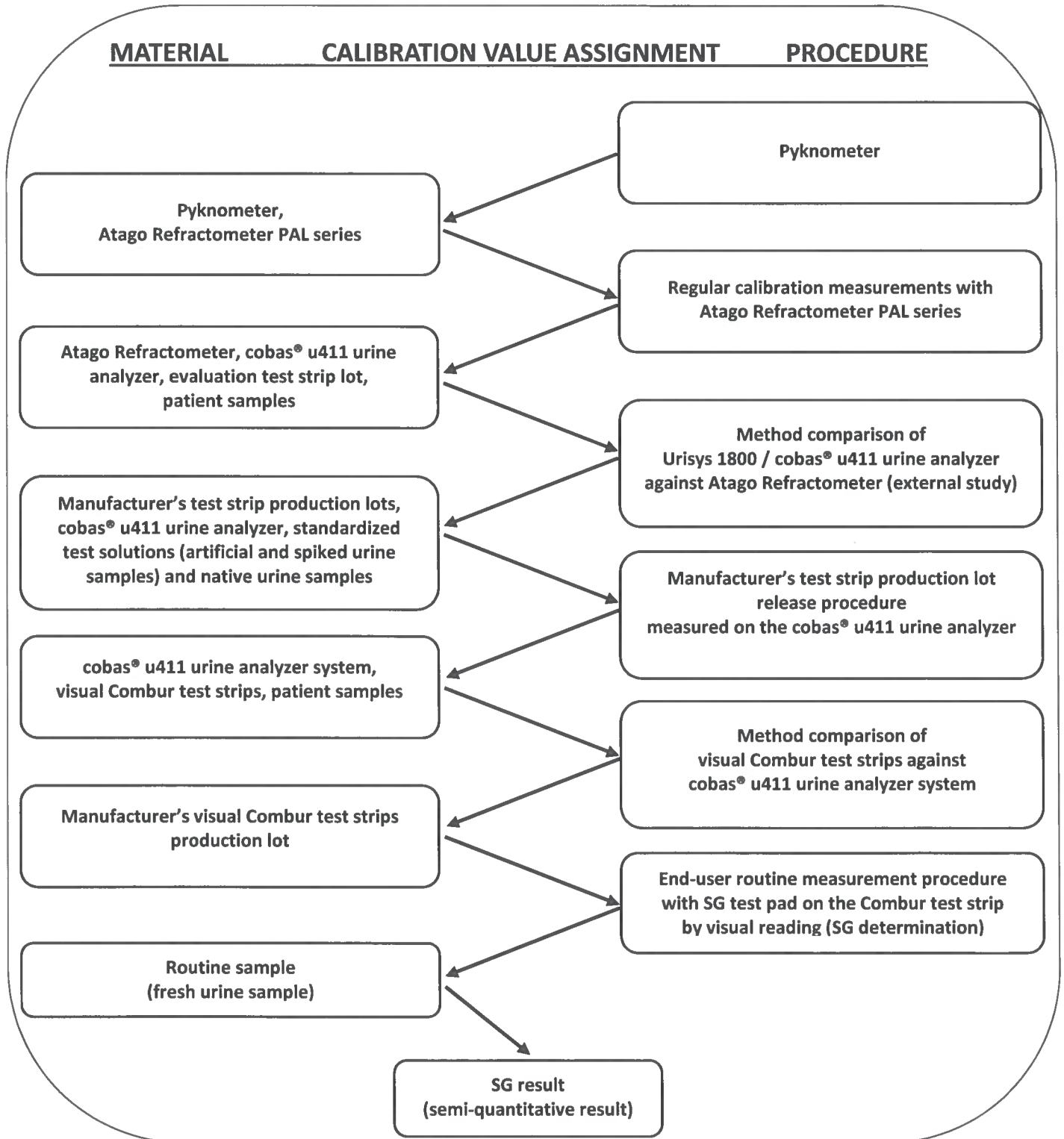


Figure: Traceability chain for the SG determination with the SG test pad on the Combur test strips