Фотографические изображения

Набор контрольных материалов для контроля качества определения фруктозамина в сыворотке и плазме крови на модулях биохнмических cobas c, в вариантах исполнения (Precinorm/Precipath Fructosamine Roche systems)

рольных материалов для контроля качества определения фруктозамина в сыворотке и плазме крови на биохимических cobas c, вариант исполнения с нормальным уровнем концентрации (Precinorm samine Roche systems)

ольных материалов для контроля качества определения фруктозамина в сыворотке и плазме крови на
мохимических cobas c, вариант исполнения с нормальным уровнем концентрации (Precinorm
mine Roche systems)

рольных материалов для контроля качества определения фруктозамина в сыворотке и плазме крови на иохимических cobas c, вариант исполнения с нормальным уровнем концентрации (Precinorm mine Roche systems)

рольных материалов для контроля качества определения фруктозамина в сыворотке и плазме крови на
охимических cobas c, вариант исполнения с нормальным уровнем концентрации (Precinorm
ine Roche systems)

контрольный Precinorm Fructosamine, флакон, объем 1,0 мл – 3 шт.;

штрих-кодом – 2 шт.;

по применению;

11834580001V10.0

Precinorm/Precipath Fructosamine cobas®

Precinorm Fructosamine / Precipath Fructosamine

REF 11098985 122 → 3 x 1 mL Control Precinorm Fructosamine

REF 11174118 122 → 3 x 1 mL Control Precipath Fructosamine

English

System information

For use on Roche/Hitachi MODULAR and **cobas c** analyzers the control code is 321 for Precinorm Fructosamine and 322 for Precipath Fructosamine.

For use on COBAS INTEGRA analyzers the system ID is 07 9164 4 for Precinorm Fructosamine and 07 9170 9 for Precipath Fructosamine.

Intended use

Precinorm Fructosamine and Precipath Fructosamine are for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.

Summary

Precinorm Fructosamine and Precipath Fructosamine are lyophilized controls based on human serum. The adjusted concentration of Precinorm Fructosamine is usually in the normal range or at the normal/pathological threshold. The adjusted concentration of Precipath Fructosamine is usually in the pathological range.

Some methods specified in the relevant value sheet may not be available in all countries.

Reagents – working solutions

Reactive components in the lyophilizate:

Fructosamine in human serum.

Non-reactive components in the lyophilizate:

Stabilizers

The concentrations of the components are lot-specific. The exact target values are given in the electronically available or enclosed value sheets.

The values are also encoded in the enclosed control barcode sheets for Roche/Hitachi MODULAR and COBAS INTEGRA analyzers.

For the **cobas c** analyzers (except for the **cobas c** 111 analyzer) the values are encoded in electronic files sent via the **cobas** link to the analyzers.

Target values and ranges

The target values were determined using the method stated in electronically available or enclosed value sheets. Determinations for Roche methods were performed under strictly standardized conditions on Roche analyzers using Roche system reagents and the Roche master calibrator. The target value specified is the median of all values obtained. The corresponding control range is calculated as the target value ± 3 standard deviations (the standard deviation being the value obtained from several target value determinations). Results should be within the defined ranges. Each laboratory should establish corrective measures to be taken if values fall outside the range.

A clinically insignificant difference may be seen between the value(s) listed on the value sheet and the value(s) obtained from the instrument readable data. This is caused by:

- the rounding of value(s) during conversion from the unit in the instrument readable data to the unit that is being used.
- the calculation of the ranges by the analyzer using the percentage values for the ranges encoded in the barcodes.

The traceability of the target value is given in the respective Method Sheets for the system reagents to be used in combination with the recommended calibrator.

Precautions and warnings

For in vitro diagnostic use.

Observe the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines. Safety data sheet available to professional user on request.

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

All human material should be considered potentially infectious. All products derived from human blood are processed exclusively from the blood of donors tested individually and shown to be free from antibodies to HCV and HIV. The testing methods used are approved by the FDA or

2020-10, V 10.0 English

cleared in compliance with the European Directive 98/79/EC, Annex II, List A.

However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen. In the event of exposure, the directives of the responsible health authorities should be followed.[1,2]

Handling

Carefully open one bottle, avoiding the loss of lyophilizate, and pipette in exactly 1.0 mL of distilled/deionized water. Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 1 hour. Avoid the formation of foam.

The enclosed barcoded labels are intended exclusively for the Roche/Hitachi MODULAR analyzers and **cobas c** systems to identify the control. Attach the barcoded labels to the tubes carrying the sample cups containing the control material.

Storage and stability

Store at 2-8 °C.

Criterion for the stability data stated by Roche:

Recovery within ± 5 % of initial value.

Stability of the lyophilized control serum:

Up to the stated expiration date at 2-8 °C.

Stability of components after reconstitution:

at 15-25 °C	7 days
at 2-8 °C	4 weeks

Store control tightly capped when not in use.

Materials provided

- See "Reagents – working solutions" section
- Barcoded labels

Materials required (but not provided)

- Roche system reagents and clinical chemistry analyzers
- General laboratory equipment

Assay

Dispense the required volume into a sample cup and analyze in the same way as patient samples.

The controls should be run daily in parallel with patient samples and after every calibration. Control intervals must be adapted to individual laboratory's requirements.

Follow the applicable government regulations and local guidelines for quality control.

References

1 Occupational Safety and Health Standards: Bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.

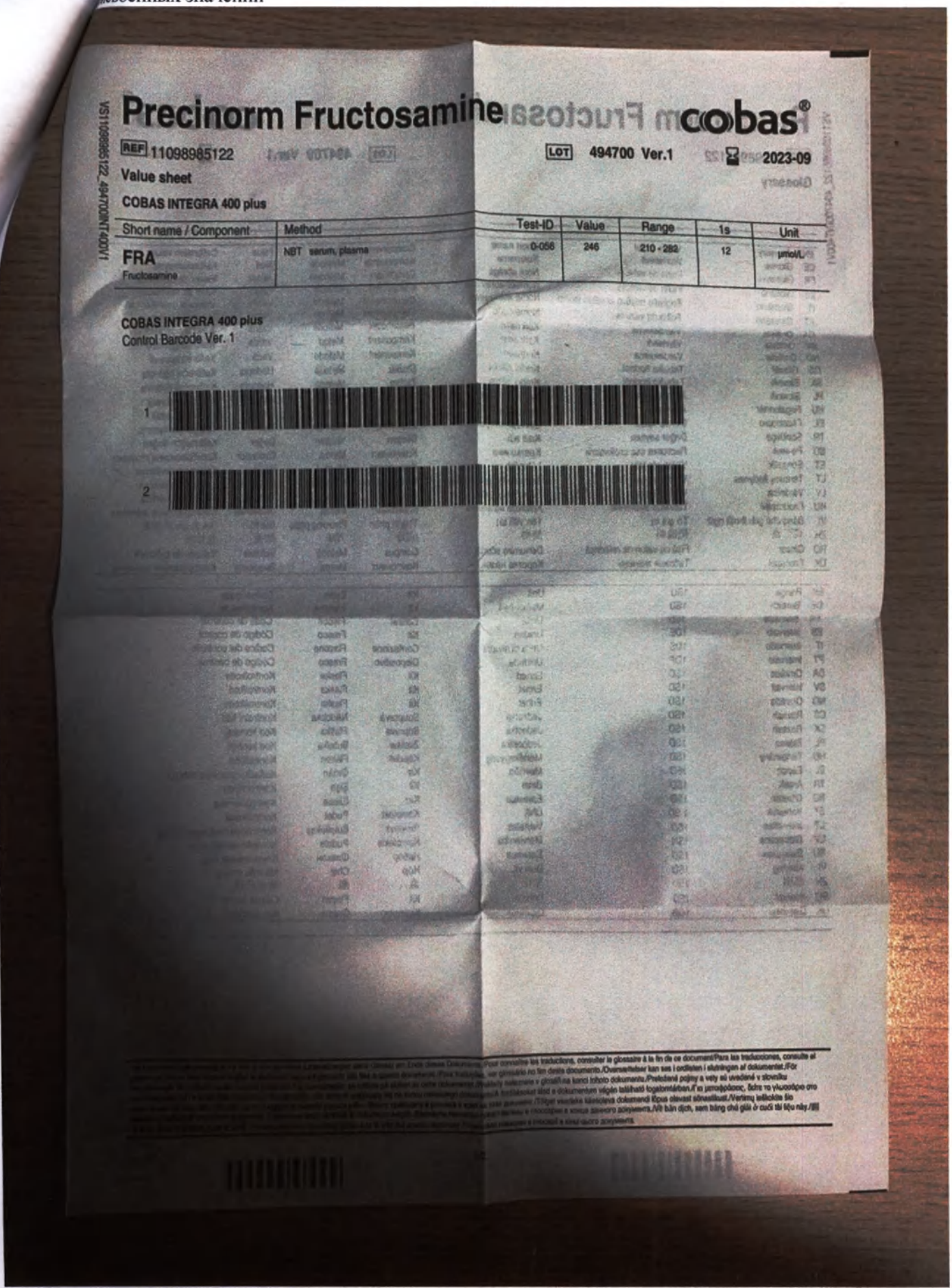
2 Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see https://usdiagnostics.roche.com for definition of symbols used):

CONTENT	Contents of kit
→	Volume after reconstitution or mixing
GTIN	Global Trade Item Number



Precinorm Fructosamine

cobas®

REF 11098985122

LOT 494700 Ver.1

2023-09

Value sheet

COBAS INTEGRA 400 plus

Short name / Component	Method	Test-ID	Value	Range	1s	Unit
FRA Fructosamine	NBT serum, plasma	0-056	246	210 - 282	12	µmol/L

COBAS INTEGRA 400 plus
Control Barcode Ver. 1

1

2

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рольных материалов для контроля качества определения фруктозамина в сыворотке и плазме крови на биохимических cobas c, вариант исполнения с патологическим уровнем концентрации (Precipath ine Roche systems)

рольных материалов для контроля качества определения фруктозамина в сыворотке и плазме крови на биохимических cobas c, вариант исполнения с патологическим уровнем концентрации (Precipath ine Roche systems)

ольных материалов для контроля качества определения фруктозамина в сыворотке и плазме крови на ахимических cobas c, вариант исполнения с патологическим уровнем концентрации (Precipath ne Roche systems)

рольных материалов для контроля качества определения фруктозамина в сыворотке и плазме крови на биохимических cobas c, вариант исполнения с патологическим уровнем концентрации (Precipath ine Roche systems)

контрольный Precipath Fructosamine, флакон, объем 1,0 мл – 3 шт.;

со штрих-кодом – 2 шт.;

по применению;

11804589001V10.0

Precinorm/Precipath Fructosamine cobas®

Precinorm Fructosamine / Precipath Fructosamine

REF 11098985 122 → 3 x 1 mL Control Precinorm Fructosamine

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English

System information

For use on Roche/Hitachi MODULAR and **cobas c** analyzers the control code is 321 for Precinorm Fructosamine and 322 for Precipath Fructosamine.

For use on COBAS INTEGRA analyzers the system ID is 07 9164 4 for Precinorm Fructosamine and 07 9170 9 for Precipath Fructosamine.

Intended use

Precinorm Fructosamine and Precipath Fructosamine are for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.

Summary

Precinorm Fructosamine and Precipath Fructosamine are lyophilized controls based on human serum. The adjusted concentration of Precinorm Fructosamine is usually in the normal range or at the normal/pathological threshold. The adjusted concentration of Precipath Fructosamine is usually in the pathological range.

Some methods specified in the relevant value sheet may not be available in all countries.

Reagents – working solutions

Reactive components in the lyophilizate:

Fructosamine in human serum.

Non-reactive components in the lyophilizate:

Stabilizers

The concentrations of the components are lot-specific. The exact target values are given in the electronically available or enclosed value sheets.

The values are also encoded in the enclosed control barcode sheets for Roche/Hitachi MODULAR and COBAS INTEGRA analyzers.

For the **cobas c** analyzers (except for the **cobas c** 111 analyzer) the values are encoded in electronic files sent via the **cobas** link to the analyzers.

Target values and ranges

The target values were determined using the method stated in electronically available or enclosed value sheets. Determinations for Roche methods were performed under strictly standardized conditions on Roche analyzers using Roche system reagents and the Roche master calibrator. The target value specified is the median of all values obtained. The corresponding control range is calculated as the target value ± 3 standard deviations (the standard deviation being the value obtained from several target value determinations). Results should be within the defined ranges. Each laboratory should establish corrective measures to be taken if values fall outside the range.

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- the calculation of the ranges by the analyzer using the percentage values for the ranges encoded in the barcodes.

The traceability of the target value is given in the respective Method Sheets for the system reagents to be used in combination with the recommended calibrator.

Precautions and warnings

For in vitro diagnostic use.

Exercise the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines.

Safety data sheet available for professional user on request.

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

All human material should be considered potentially infectious. All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV. The testing methods used (assays approved by the FDA or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.

However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen. In the event of exposure, the directives of the responsible health authorities should be followed.[1,2]

Handling

Carefully open one bottle, avoiding the loss of lyophilizate, and pipette in exactly 1.0 mL of distilled/deionized water. Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 1 hour. Avoid the formation of foam.

The enclosed barcoded labels are intended exclusively for the Roche/Hitachi MODULAR analyzers and **cobas c** systems to identify the control. Attach the barcoded labels to the tubes carrying the sample cups containing the control material.

Storage and stability

Store at 2-8 °C.

Criterion for the stability data stated by Roche:

Recovery within ± 5 % of initial value.

Stability of the lyophilized control serum:

Up to the stated expiration date at 2-8 °C.

Stability of components after reconstitution:

at 15-25 °C	7 days
at 2-8 °C	4 weeks

Store control tightly capped when not in use.

Materials provided

- See "Reagents – working solutions" section
- Barcoded labels

Materials required (but not provided)

- Roche system reagents and clinical chemistry analyzers
- General laboratory equipment

Assay

Dispense the required volume into a sample cup and analyze in the same way as patient samples.

The controls should be run daily in parallel with patient samples and after every calibration. Control intervals must be adapted to individual laboratory's requirements.

Follow the applicable government regulations and local guidelines for quality control.

References

1 Occupational Safety and Health Standards: Bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.

2 Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

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Symbols

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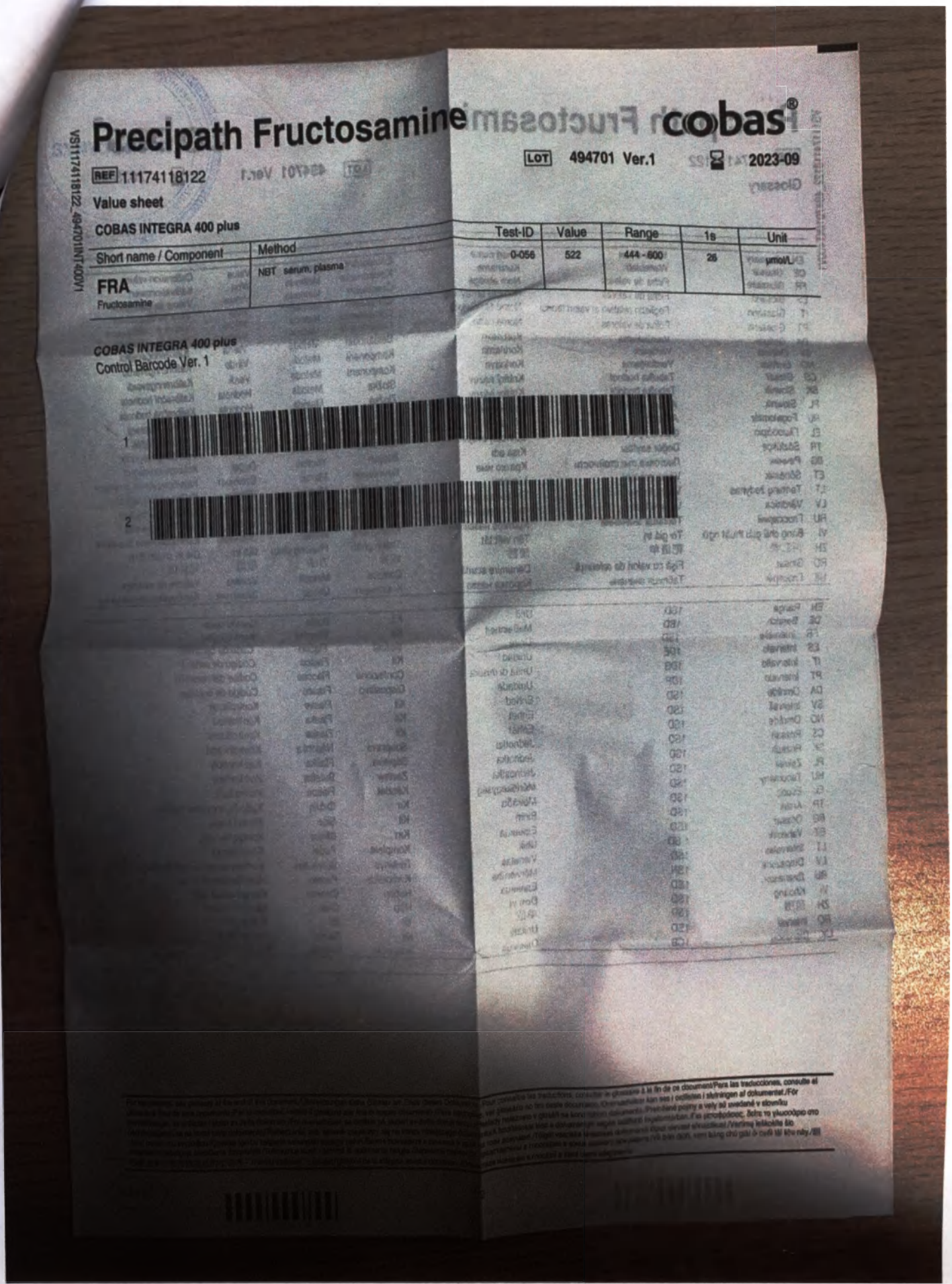

Precipath Fructosamine

cobas®

REF 11174118122

LOT 494701 Ver.1

2023-09

Value sheet

COBAS INTEGRA 400 plus

Short name / Component	Method
FRA Fructosamine	NBT serum, plasma

Test-ID	Value	Range	1s	Unit
0-056	522	444 - 600	26	µmol/L

COBAS INTEGRA 400 plus
Control Barcode Ver. 1

1

2

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