# Pointe Glucose (Oxidase) Reagent Set

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## Intended Use
Pointe Glucose (Oxidase) Reagent Set is intended for research use only when performing the quantitative measurement of glucose in urine using the Yumizen C230 and Yumizen C240 analyzers.

## Clinical Significance
The examination of glucose in urine is a rapid, non-invasive screening tool for the diagnosis and treatment of diabetes mellitus.[1]

## Test Summary
Early enzymatic methods for glucose determination used Glucose Oxidase to catalyze the oxidation of glucose to hydrogen peroxide and gluconic acid.[2] The hydrogen peroxide that is formed is measured by the oxidation of a chromagen.[3] Many chromagens were investigated but many were discarded because of possible carcinogenicity, toxicity, instability or because they were affected by many interfering substances. Trinder[4] modified Emerson[5] to develop an efficient peroxidase-phenol-aminophenazone system for the quantitation of hydrogen peroxide by formulation of a red quinoneimine dye. This method is less influenced by interfering substances and does not suffer from the many drawbacks of earlier methods.

## Principle

$$\text{D-Glucose} + H_2O + O_2 \xrightarrow{\text{Glucose Oxidase}} H_2O_2 + \text{D-Gluconate}$$

$$H_2O_2 + \text{4-AAP} + \text{Phenol} \xrightarrow{\text{POD}} \text{Quinoneimine dye} + H_2O$$

Glucose is oxidized by glucose oxidase to gluconate and hydrogen peroxide. Phenol + 4-AAP + hydrogen peroxide, in the presence of peroxidase, produces a quinoneimine dye that is measured at 500nm. The absorbance at 500nm is proportional to the concentration of glucose in the sample.

## Reagent Composition
Glucose Oxidase (microbial) 12,000 u/l, Peroxidase (horseradish) > 1,000 u/l, 4-AAP >0.3mM, Phenol 4mM, Buffer, pH 7.4 ± 0.1, non-reactive stabilizers, preservative. See "Precautions".

## Reagent Preparation
The reagent is ready to use.

## Reagent Storage and Stability
1. The reagent should be stored refrigerated at 2-8°C.
2. The reagent is stable until the indicated expiration date when stored as directed.

## Precautions
1. The reagent should not be used if it has developed turbidity or other evidence of microbial growth.
2. The reagent should not be used if it fails to meet linearity claims or fails to recover control values in the stated range.
3. All specimens and controls should be handled as potentially infectious, using safe laboratory procedures. (NCCLS M29-T2).[6]

## Specimen Collection and Storage
1. For 24-hours collection urine, 5 mL of glacial acetic acid may be added to the container before starting the collection. The final pH of urine between 4-5 inhibits bacterial activity. Without preservatives, loss of glucose can be -40% after 24 hours at room temperature.[1]
2. Specimens should be collected as per NCCLS document GP16-A3.[7]

## Interference
A summary of the influence of drugs on clinical laboratory tests on glucose testing may be found by consulting Young, D.S.[8]

## Materials Provided
Glucose (Oxidase) Reagent.

## Materials Required but not Provided
1. Yumizen C230 / Yumizen C240 Analyzer
2. Yumizen C230 / Yumizen C240 Operation manual
3. Chemistry Calibrator, catalog number C7506-50
4. Human Urine, catalog number P7582-CTL

## Test Parameters

| | | | |
|---|---|---|---|
| Chem: | GLUC OX | Chemistry: Glucose (Oxidase) | |
| Chemistry No.: | | Print Name: GLUC OX | |
| Reaction Type: | Endpoint | Reaction Direction: Positive | |
| Pri. Wave: | 510 nm | Sec. Wave: 670 nm | |
| Decimal.: | 0 | Samp. Type: Urine | |
| Blank Time: | | Reaction Time: 21 | 22 |
| Unit: | mg/dL | Incubation Time: 0 | |

| | Sample Vol. | Aspirated | Diluent | Reagent Vol. | Diluent |
|---|---|---|---|---|---|
| Standard; | 2 uL | uL | uL | R1: 200 uL | uL |
| Decreased; | | uL | uL | | |
| Increased; | | uL | uL | | |

| | | | | | |
|---|---|---|---|---|---|
| Linearity Range (Standard); 0.0-500 | | | Linearity Limit: | | |
| Linearity Range (Decreased): | | | Substrate Depletion: | | |
| Linearity Range (Increased): | | | Mixed Blank Abs.: | -40000 | 40000 |
| R1 Blank Abs.: | -40000 | 40000 | On-board Stability: | 30 | Day (s) |
| Blank Response | -40000 | 40000 | Reagent Alarm Limit: | 10 | |
| Twin Chemistry: | | | | | |

Prozone Check:

| | | |
|---|---|---|
| Q1: | Q2: | Q3: |
| Q4: | PC: | ABS: |

Use Qualitative Result:

| | | |
|---|---|---|
| | Range: | Flag: |

Slope Offset:

| Slope | Offset | Uint |
|---|---|---|
| 1 | 0 | mg/dL |

Pretreatment:

| | | | |
|---|---|---|---|
| Pretreat Sample Vol.: | uL | Pretreat Reagent Vol.: | uL |

Ref. Range:

| Sample Type: | Gender: | Age Range: | Ref. Range: | Critical Range: | Unit: |
|---|---|---|---|---|---|

## Calibration Setup Parameters

Chem: GLUC OX
Calibration Setting
Math Model: Two-Point Linear
Factor: Replicates: 2
Acceptance Limits
Cal Time:
Slope Diff: SD:
Sensitivity: Repeatability: * User Defined
Deter Coeff:
Auto Calib.
□ Cal Time

| Calibrator | Conc. | Pos | Lot No. |
|---|---|---|---|
| Water | 0.0 | W | |
| Chem Cal | * | * | |
| | | | |

# Pointe Glucose (Oxidase) Reagent Set

## Limitations
The Linearity limit for glucose in sample is 500mg/dl.

## Calibration
Calibration material should be used to calibrate the procedure. The frequency of calibration using an automated system is dependent on the system and the parameters used. If control results are found to be out of range, the test may need to be re-calibrated.

## Quality Control
A normal and abnormal concentration control should be analyzed as required in accordance with local, state and federal guidelines. The results should fall within the acceptable range as established by the laboratory.

## Reference Intervals[1]
0-15 mg/dL (0.1-0.8 mmol/L) , less than 0.5g/day in a 24h sample.
These values are suggested guidelines. It is recommended that each laboratory establish the normal range for the area in which it is located.

## Performance Characteristics
1. Linearity: 0.0- 500.0 mg/dl
2. Comparison: A study was performed between the Yumizen 200 series and a similar analyzer using this method, resulting in a correlation coefficient of 0.9991 with a regression equation of y=1.002 x + 1.67 (n=33).
3. Precision: Precision studies were performed using the Yumizen 200 series analyzer following a modification of the guidelines which are contained in NCCLS document EP5-T2.[9]

| | Within Run | |
|---|---|---|
| **Mean** | **S.D.** | **C.V.%** |
| 90.3 | 0.5 | 0.5 |
| 258.4 | 1.8 | 0.7 |
| 374.1 | 2.4 | 0.6 |

4. Sensitivity: The limit of blank (LOB): 0.96 mg/dl.

## References

1. Nader Rifai, Andrea Rita Horvath, Carl T. Wittwer. Tietz textbook of clinical chemistry and molecular diagnostics. Sixth Edition. St. Louis : Elsevier, (2018), p. 530-531, 1764
2. Keston, A.S., Abstr., 129th Meeting Amer. Chem. Soc., p 31 (1956).
3. Teller, J.D., Abstr., 130th Meeting Amer. Chem. Soc., Atlantic City, N.J., p 69c (1956).
4. Trinder, P., Ann. Clin. Biochem. 6:24 (1969).
5. Emerson, E.J., et al, J. Org. Chem. 3:153 (1938) and 8:417 (1943).
6. NCCLS document "Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids, and Tissue", 2nd Ed. (1991).
7. NCCLS. Urinalysis and collection, transportation and preservation of urine specimen; Approved guideline -3nd Edition, NCCLS document GP16-A3 (2009)
8. Young DS. Effects of Drugs on Clinical Laboratory Tests. 4th Edition, Washington, DC, AACC Press (1995) 3; 291-294
9. NCCLS document "Evaluation of Precision Performance of Clinical Chemistry Devices", 2nd Ed. (1992).


## Symbol Key
| | |
|---|---|
| Use by (YYYY-MM-DD) | LOT Lot and batch code |
| REF Catalog number | Manufacturer |
| Temperature limitation | Consult instructions for use |

Research use only.

## Certified to Perform Reagents
The Pointe reagents are certified to be manufactured according to specified parameters. Any Pointe reagent product not meeting specifications through its listed expiration date will be remedied immediately without charge.

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REF 12-G7517-160

Manufactured by
HORIBA Instruments Incorporated - Pointe Brand
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