

Liquichek™ Hematology-16 Control

Low, Normal and High

| | | | | | | | | | |
|------------|------------------------------|----------|----|------------|-----------------------|------------|-------|--------|-------|
| REF | 760 Trilevel | 6 x 3 mL | CE | IVD | EXP 2022-10-09 | LOT | 81480 | Low | 81481 |
| | 761 Low | 6 x 3 mL | | | | | | Normal | 81482 |
| | 762 Normal | 6 x 3 mL | | | | | | High | 81483 |
| | 763 High | 6 x 3 mL | | | | | | | |
| | 760X Trilevel MiniPak | 3 x 3 mL | | | | | | | |

ENGLISH

INTENDED USE
Liquichek Hematology-16 Control is a hematology reference control used in monitoring determinations of blood cell values on all impedance cell counters.

SUMMARY AND PRINCIPLE
The use of quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices. Three levels of control are available to allow monitoring of performance.
For customers in Germany: Quality control materials are required for assessment of laboratory performance as described in the "Guideline for Quality Assurance of Medical Laboratory Examinations following the German Medical Association" (Rili-BÄK regulation).

REAGENT
This product is a suspension of stabilized lysable human erythrocytes, simulated platelet components, simulated white cells and constituents of animal origin in a medium containing stabilizers and preservatives. The control is provided in liquid form for convenience.

STORAGE AND STABILITY
This product will be stable until the expiration date when stored unopened at 2 to 8°C. Once opened, this product will be stable for 21 days when stored tightly capped at 2 to 8°C.

This product is shipped under refrigerated conditions.

DO NOT FREEZE.

PROCEDURE
This product should be treated and analyzed the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit, or reagent being used.

1. Remove tubes from the refrigerator and allow to warm to room temperature (15 to 30°C) for 15 minutes before mixing.
2. To mix, hold a tube horizontally between the palms of the hands. **Do not pre-mix on a mechanical mixer.**
 - (a) Roll the tube back and forth for 20 to 30 seconds; occasionally invert the tube. Mix vigorously, but do not shake.
 - (b) Continue to mix in this manner until the red cells are completely suspended. Tubes stored for a long time may require extra mixing.
 - (c) Gently invert the tube 8 to 10 times immediately before sampling.
3. Analyze the sample as instructed in the Quality Control section of the Operator's Manual for your instrument.
4. After sampling:
 - (a) If tube has been opened for sampling, clean residual material from the cap and tube rim with a lint-free tissue. Replace the cap tightly.
 - (b) Return tubes to refrigerator within 30 minutes of use.

If instrument includes an autosampler/mixer, **mix first as directed above**, then place the tubes in a cassette and place on the instrument.
Dispose of any discarded materials in accordance with the requirements of your local waste management authorities. In the event of damage to packaging, contact the local Bio-Rad Laboratories Sales Office or Bio-Rad Laboratories Technical Services.

- LIMITATIONS**
1. This product should not be used past the expiration date.
 2. This product is not intended for use as a standard.
 3. Inability to obtain expected values may indicate product deterioration. Discoloration of the product may be caused by overheating or freezing during shipping or storage.
 4. A manual differential analysis of white blood cells cannot be performed with this product.
 5. Coloration of the Liquichek Hematology-16 Control is a result of the manufacturing process. Performance of the product is determined by test results relative to expected values. Contact Bio-Rad Laboratories if test results are outside of published insert values.

ASSIGNMENT OF VALUES
The mean values printed in this insert were derived from replicate analyses and are specific for this lot of product. The tests listed were performed by using manufacturer supported reagents and a representative sampling of this lot of product. Individual laboratory means should fall within the corresponding acceptable range; however, laboratory means may vary from the listed values during the life of this product. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation calibrating method and reagents. It is recommended that each laboratory establish its own means and acceptable ranges and use those provided only as guides.

Note: Azide-free reagents were used in analyzing this product. When azide-containing reagents are used with this product, differences in MCV, HCT and MCHC can be expected.

Refer to www.gcnet.com for insert update information.

SPECIFIC PERFORMANCE CHARACTERISTICS
This product is a stabilized liquid product manufactured under rigid quality control standards. To obtain consistent vial-to-vial assay values, this product requires proper storage and handling as described.

CÔNG TY
 TNHH
 THƯƠNG MẠI
SIXMURS HTH
 VIỆT NAM
 Q. NAM TỬ LIÊM - TP. HÀ NỘI

GIÁM ĐỐC
Phạm Thị Thu Hằng

| | | | | | | | | | |
|----------------|---------------------|------------------------------------|---------------------|------------|---|--------------|---------------------------|------------------------------|------------------------|
| REF | CE | IVD | EXP | LOT | | | EC REP | | |
| Catalog Number | European Conformity | In Vitro Diagnostic Medical Device | Use by (YYYY-MM-DD) | Lot Number | Caution, Consult Accompanying Documents | Manufacturer | Authorized Representative | Consult Instructions for Use | Temperature Limitation |



WARNING /

ENGLISH

Biological source material. Treat as potentially infectious.

Each human donor unit used to manufacture this product was tested as required by FDA accepted methods. Tests results were non-reactive or negative for evidence of infection due to Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV). This product may also contain other human source materials for which there are no approved tests. In accordance with good laboratory practice, all human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.



Danger

Contains ethanol and 5-chloro-2-methyl-2H-isothiazol-3-one

Hazard (H) and Precautionary (P) Statements

H317 May cause an allergic skin reaction. **H350** May cause cancer. **P261** Avoid breathing dust / fume / gas / mist / vapors / spray. **P280** Wear protective gloves / protective clothing / eye protection / face protection. **P312** Call a poison center / doctor if you feel unwell. **P363** Wash contaminated clothing before reuse. **P333+P313** If skin irritation or rash occurs: Get medical advice / attention. **P302+P352** If on skin: Wash with plenty of soap and water.

Safety Data Sheet (SDS) available for professional users on www.bio-rad.com.

Bio-Rad Laboratories comprehensive line of quality controls and QC data management solutions.

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Toxicology: Specialty Controls
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USA: 1-800-224-6723 | www.bio-rad.com/qualitycontrol

| GLOSSARY | |
|--|--|
| PARAMETERS | |
| GRAN (Granulocytes) | |
| HCT (Hematocrit) | |
| HGB (Hemoglobin) | |
| LYMPH (Lymphocytes) | |
| MCH (Mean Corpuscular Hemoglobin) | |
| MCHC (Mean Corpuscular Hemoglobin Concentration) | |
| MCV (Mean Corpuscular Volume) | |
| MID (Mid-Sized Cells) | |
| MONO (Monocytes) | |
| MPV (Mean Platelet Volume) | |
| PLT (Platelets) | |
| RBC (Red Blood Cells) | |
| RDW (Red Blood Cell Distribution Width) | |
| WBC (White Blood Cells) | |
| TERMS | |
| Auxiliary Methods | |
| High | |
| Low | |
| Manual | |
| Mean | |
| Normal | |
| Open-Tube Sampling | |
| Range | |
| Units | |

INSTRUMENT

Gerät // Appareil // Strumento // Instrumento // Instrument // Instrument // Cihaz // 機器

| | Units | Low - 81481 | | Normal - 81482 | | High - 81483 | | SI | Low - 81481 | | Normal - 81482 | | High - 81483 | |
|---|------------|-------------|--------|----------------|--------|--------------|--------|---------------------|-------------|---------|----------------|---------|--------------|---------|
| | | Mean | Range | Mean | Range | Mean | Range | | Mean | Range | Mean | Range | Mean | Range |
| ABBOTT CELL-DYN EMERALD | | | | | | | | | | | | | | |
| WBC | K/ μ L | 3.7 | ± 0.4 | 9.7 | ± 1.0 | 20.5 | ± 2.0 | 10 ⁹ /L | 3.7 | ± 0.4 | 9.7 | ± 1.0 | 20.5 | ± 2.0 |
| LYMPH # | K/ μ L | 2.1 | ± 0.2 | 4.9 | ± 0.3 | 8.3 | ± 0.7 | 10 ⁹ /L | 2.1 | ± 0.2 | 4.9 | ± 0.3 | 8.3 | ± 0.7 |
| MID # | K/ μ L | 0.6 | ± 0.2 | 0.8 | ± 0.4 | 1.0 | ± 0.8 | 10 ⁹ /L | 0.6 | ± 0.2 | 0.8 | ± 0.4 | 1.0 | ± 0.8 |
| GRAN # | K/ μ L | 1.0 | ± 0.5 | 4.0 | ± 1.3 | 11.2 | ± 2.6 | 10 ⁹ /L | 1.0 | ± 0.5 | 4.0 | ± 1.3 | 11.2 | ± 2.6 |
| LYMPH | % | 58.4 | ± 4.0 | 50.2 | ± 3.0 | 40.4 | ± 3.0 | % | 58.4 | ± 4.0 | 50.2 | ± 3.0 | 40.4 | ± 3.0 |
| MID | % | 15.9 | ± 4.0 | 8.0 | ± 3.0 | 4.7 | ± 3.0 | % | 15.9 | ± 4.0 | 8.0 | ± 3.0 | 4.7 | ± 3.0 |
| GRAN | % | 25.7 | ± 5.0 | 41.8 | ± 5.0 | 54.9 | ± 4.0 | % | 25.7 | ± 5.0 | 41.8 | ± 5.0 | 54.9 | ± 4.0 |
| RBC | M/ μ L | 2.47 | ± 0.15 | 4.33 | ± 0.18 | 5.11 | ± 0.20 | 10 ¹² /L | 2.47 | ± 0.15 | 4.33 | ± 0.18 | 5.11 | ± 0.20 |
| HGB | g/dL | 6.3 | ± 0.4 | 12.6 | ± 0.5 | 16.2 | ± 0.6 | g/L | 63 | ± 4 | 126 | ± 5 | 162 | ± 6 |
| HCT | % | 19.8 | ± 2.7 | 38.7 | ± 3.3 | 49.4 | ± 4.0 | L/L | 0.198 | ± 0.027 | 0.387 | ± 0.033 | 0.494 | ± 0.040 |
| MCV | fL | 80.2 | ± 6.0 | 89.4 | ± 4.0 | 96.7 | ± 4.0 | fL | 80.2 | ± 6.0 | 89.4 | ± 4.0 | 96.7 | ± 4.0 |
| MCH | pg | 25.5 | ± 3.2 | 29.1 | ± 2.4 | 31.7 | ± 2.4 | pg | 25.5 | ± 3.2 | 29.1 | ± 2.4 | 31.7 | ± 2.4 |
| MCHC | g/dL | 31.8 | ± 6.5 | 32.6 | ± 4.1 | 32.8 | ± 3.9 | g/L | 318 | ± 65 | 326 | ± 41 | 328 | ± 39 |
| RDW | % | 16.7 | ± 2.0 | 14.2 | ± 2.2 | 13.1 | ± 2.5 | % | 16.7 | ± 2.0 | 14.2 | ± 2.2 | 13.1 | ± 2.5 |
| PLT | K/ μ L | 53 | ± 18 | 234 | ± 35 | 475 | ± 60 | 10 ⁹ /L | 53 | ± 18 | 234 | ± 35 | 475 | ± 60 |
| MPV | fL | 9.1 | ± 2.0 | 9.1 | ± 2.0 | 9.2 | ± 2.0 | fL | 9.1 | ± 2.0 | 9.1 | ± 2.0 | 9.2 | ± 2.0 |
| BECKMAN COULTER A^oT DIFF / COULTER A^oT DIFF2 (3-PART DIFF) | | | | | | | | | | | | | | |
| WBC | K/ μ L | 3.5 | ± 0.6 | 9.5 | ± 1.0 | 20.9 | ± 2.5 | 10 ⁹ /L | 3.5 | ± 0.6 | 9.5 | ± 1.0 | 20.9 | ± 2.5 |
| RBC | M/ μ L | 2.44 | ± 0.15 | 4.26 | ± 0.20 | 5.01 | ± 0.25 | 10 ¹² /L | 2.44 | ± 0.15 | 4.26 | ± 0.20 | 5.01 | ± 0.25 |
| HGB | g/dL | 6.1 | ± 0.3 | 11.9 | ± 0.4 | 15.5 | ± 0.6 | g/L | 61 | ± 3 | 119 | ± 4 | 155 | ± 6 |
| HCT | % | 17.9 | ± 2.6 | 35.4 | ± 4.2 | 45.1 | ± 5.3 | L/L | 0.179 | ± 0.026 | 0.354 | ± 0.042 | 0.451 | ± 0.053 |
| MCV | fL | 73.4 | ± 6.0 | 83.1 | ± 6.0 | 90.0 | ± 6.0 | fL | 73.4 | ± 6.0 | 83.1 | ± 6.0 | 90.0 | ± 6.0 |
| MCH | pg | 25.0 | ± 2.8 | 27.9 | ± 2.3 | 30.9 | ± 2.7 | pg | 25.0 | ± 2.8 | 27.9 | ± 2.3 | 30.9 | ± 2.7 |
| MCHC | g/dL | 34.1 | ± 6.7 | 33.6 | ± 5.2 | 34.4 | ± 5.4 | g/L | 341 | ± 67 | 336 | ± 52 | 344 | ± 54 |
| RDW | % | 18.0 | ± 5.0 | 14.2 | ± 5.0 | 13.4 | ± 5.0 | % | 18.0 | ± 5.0 | 14.2 | ± 5.0 | 13.4 | ± 5.0 |
| PLT | K/ μ L | 54 | ± 15 | 227 | ± 30 | 487 | ± 60 | 10 ⁹ /L | 54 | ± 15 | 227 | ± 30 | 487 | ± 60 |
| MPV | fL | 9.6 | ± 1.5 | 9.7 | ± 1.5 | 9.8 | ± 1.5 | fL | 9.6 | ± 1.5 | 9.7 | ± 1.5 | 9.8 | ± 1.5 |
| LYMPH | % | 62.3 | ± 10.0 | 54.6 | ± 10.0 | 46.2 | ± 10.0 | % | 62.3 | ± 10.0 | 54.6 | ± 10.0 | 46.2 | ± 10.0 |
| MONO | % | 16.4 | ± 5.0 | 8.8 | ± 5.0 | 5.6 | ± 4.0 | % | 16.4 | ± 5.0 | 8.8 | ± 5.0 | 5.6 | ± 4.0 |
| GRAN | % | 21.3 | ± 8.0 | 36.6 | ± 10.0 | 48.2 | ± 10.0 | % | 21.3 | ± 8.0 | 36.6 | ± 10.0 | 48.2 | ± 10.0 |
| LYMPH # | K/ μ L | 2.2 | ± 0.5 | 5.2 | ± 0.8 | 9.7 | ± 1.5 | 10 ⁹ /L | 2.2 | ± 0.5 | 5.2 | ± 0.8 | 9.7 | ± 1.5 |
| MONO # | K/ μ L | 0.6 | ± 0.3 | 0.8 | ± 0.6 | 1.2 | ± 1.0 | 10 ⁹ /L | 0.6 | ± 0.3 | 0.8 | ± 0.6 | 1.2 | ± 1.0 |
| GRAN # | K/ μ L | 0.7 | ± 0.4 | 3.5 | ± 1.0 | 10.0 | ± 2.0 | 10 ⁹ /L | 0.7 | ± 0.4 | 3.5 | ± 1.0 | 10.0 | ± 2.0 |
| MEDONIC M-SERIES | | | | | | | | | | | | | | |
| WBC | K/ μ L | 3.1 | ± 0.6 | 8.8 | ± 0.6 | 19.5 | ± 2.5 | 10 ⁹ /L | 3.1 | ± 0.6 | 8.8 | ± 0.6 | 19.5 | ± 2.5 |
| RBC | M/ μ L | 2.44 | ± 0.15 | 4.36 | ± 0.20 | 5.18 | ± 0.25 | 10 ¹² /L | 2.44 | ± 0.15 | 4.36 | ± 0.20 | 5.18 | ± 0.25 |
| HGB | g/dL | 6.4 | ± 0.3 | 12.4 | ± 0.4 | 16.0 | ± 0.6 | g/L | 64 | ± 3 | 124 | ± 4 | 160 | ± 6 |
| HCT | % | 17.1 | ± 2.5 | 35.1 | ± 4.2 | 46.1 | ± 5.3 | L/L | 0.171 | ± 0.025 | 0.351 | ± 0.042 | 0.461 | ± 0.053 |
| MCV | fL | 70.1 | ± 6.0 | 80.5 | ± 6.0 | 89.0 | ± 6.0 | fL | 70.1 | ± 6.0 | 80.5 | ± 6.0 | 89.0 | ± 6.0 |
| MCH | pg | 26.2 | ± 2.9 | 28.4 | ± 2.2 | 30.9 | ± 2.7 | pg | 26.2 | ± 2.9 | 28.4 | ± 2.2 | 30.9 | ± 2.7 |
| MCHC | g/dL | 37.4 | ± 7.4 | 35.3 | ± 5.5 | 34.7 | ± 5.4 | g/L | 374 | ± 74 | 353 | ± 55 | 347 | ± 54 |
| PLT | K/ μ L | 61.0 | ± 15 | 246 | ± 30 | 524 | ± 60 | 10 ⁹ /L | 61 | ± 15 | 246 | ± 30 | 524 | ± 60 |
| MPV | fL | 9.3 | ± 1.5 | 9.1 | ± 1.5 | 9.1 | ± 1.5 | fL | 9.3 | ± 1.5 | 9.1 | ± 1.5 | 9.1 | ± 1.5 |
| RDW | % | 15.7 | ± 5.0 | 13.5 | ± 5.0 | 13.1 | ± 5.0 | % | 15.7 | ± 5.0 | 13.5 | ± 5.0 | 13.1 | ± 5.0 |
| LYMF | % | 69.0 | ± 10.0 | 51.7 | ± 10.0 | 40.1 | ± 9.0 | % | 69.0 | ± 10.0 | 51.7 | ± 10.0 | 40.1 | ± 9.0 |
| MID | % | 5.2 | ± 5.2 | 3.7 | ± 3.7 | 2.5 | ± 2.5 | % | 5.2 | ± 5.2 | 3.7 | ± 3.7 | 2.5 | ± 2.5 |
| GRAN | % | 27.6 | ± 10.0 | 46.0 | ± 5.0 | 58.0 | ± 5.0 | % | 27.6 | ± 10.0 | 46.0 | ± 5.0 | 58.0 | ± 5.0 |
| LYMF | K/ μ L | 2.1 | ± 0.6 | 4.5 | ± 1.2 | 7.8 | ± 2.0 | 10 ⁹ /L | 2.1 | ± 0.6 | 4.5 | ± 1.2 | 7.8 | ± 2.0 |
| MID | K/ μ L | 0.2 | ± 0.2 | 0.3 | ± 0.3 | 0.6 | ± 0.6 | 10 ⁹ /L | 0.2 | ± 0.2 | 0.3 | ± 0.3 | 0.6 | ± 0.6 |
| GRAN | K/ μ L | 0.9 | ± 0.5 | 4.1 | ± 0.7 | 11.3 | ± 2.1 | 10 ⁹ /L | 0.9 | ± 0.5 | 4.1 | ± 0.7 | 11.3 | ± 2.1 |
| SYSMEX XS-1000i | | | | | | | | | | | | | | |
| WBC | K/ μ L | 3.1 | ± 0.5 | 9.3 | ± 0.7 | 21.6 | ± 2.0 | 10 ⁹ /L | 3.1 | ± 0.5 | 9.3 | ± 0.7 | 21.6 | ± 2.0 |
| RBC | M/ μ L | 2.45 | ± 0.15 | 4.38 | ± 0.24 | 5.16 | ± 0.30 | 10 ¹² /L | 2.45 | ± 0.15 | 4.38 | ± 0.24 | 5.16 | ± 0.30 |
| HGB | g/dL | 6.0 | ± 0.4 | 12.1 | ± 0.5 | 15.8 | ± 0.6 | g/L | 60 | ± 4 | 121 | ± 5 | 158 | ± 6 |
| HCT | % | 18.9 | ± 2.6 | 38.5 | ± 4.3 | 49.7 | ± 5.5 | L/L | 0.189 | ± 0.026 | 0.385 | ± 0.043 | 0.497 | ± 0.055 |
| MCV | fL | 77 | ± 6 | 88 | ± 5 | 96 | ± 5 | fL | 77 | ± 6 | 88 | ± 5 | 96 | ± 5 |
| MCH | pg | 24.5 | ± 3.1 | 27.6 | ± 2.7 | 30.6 | ± 3.0 | pg | 24.5 | ± 3.1 | 27.6 | ± 2.7 | 30.6 | ± 3.0 |
| MCHC | g/dL | 31.7 | ± 6.7 | 31.4 | ± 4.9 | 31.8 | ± 4.8 | g/L | 317 | ± 67 | 314 | ± 49 | 318 | ± 48 |
| RDW-SD | fL | 52.9 | ± 10.0 | 51.5 | ± 10.0 | 53.0 | ± 10.0 | fL | 52.9 | ± 10.0 | 51.5 | ± 10.0 | 53.0 | ± 10.0 |

| | Units | Low - 81481 | | Normal - 81482 | | High - 81483 | | SI | Low - 81481 | | Normal - 81482 | | High - 81483 | |
|--|------------|-------------|-------|----------------|-------|--------------|-------|---------------------|-------------|---------|----------------|---------|--------------|---------|
| | | Mean | Range | Mean | Range | Mean | Range | | Mean | Range | Mean | Range | Mean | Range |
| SYSMEX XS-1000i (continued) | | | | | | | | | | | | | | |
| RDW-CV | % | 19.8 | ± 5.0 | 16.7 | ± 5.0 | 16.2 | ± 5.0 | % | 19.8 | ± 5.0 | 16.7 | ± 5.0 | 16.2 | ± 5.0 |
| PLT | K/ μ L | 58 | ± 25 | 239 | ± 40 | 509 | ± 60 | 10 ⁹ /L | 58 | ± 25 | 239 | ± 40 | 509 | ± 60 |
| MPV | fL | 9.2 | ± 3.0 | 9.7 | ± 3.0 | 10.0 | ± 3.0 | fL | 9.2 | ± 3.0 | 9.7 | ± 3.0 | 10.0 | ± 3.0 |
| SYSMEX XT-1800i / XT-2000i (OPEN-TUBE SAMPLING) | | | | | | | | | | | | | | |
| WBC | K/ μ L | \$ | | \$ | | \$ | | 10 ⁹ /L | \$ | | \$ | | \$ | |
| RBC | M/ μ L | \$ | | \$ | | \$ | | 10 ¹² /L | \$ | | \$ | | \$ | |
| HGB | g/dL | \$ | | \$ | | \$ | | g/L | \$ | | \$ | | \$ | |
| HCT | % | \$ | | \$ | | \$ | | L/L | \$ | | \$ | | \$ | |
| MCV | fL | \$ | | \$ | | \$ | | fL | \$ | | \$ | | \$ | |
| MCH | pg | \$ | | \$ | | \$ | | pg | \$ | | \$ | | \$ | |
| MCHC | g/dL | \$ | | \$ | | \$ | | g/L | \$ | | \$ | | \$ | |
| RDW-SD | fL | \$ | | \$ | | \$ | | fL | \$ | | \$ | | \$ | |
| RDW-CV | % | \$ | | \$ | | \$ | | % | \$ | | \$ | | \$ | |
| PLT | K/ μ L | \$ | | \$ | | \$ | | 10 ⁹ /L | \$ | | \$ | | \$ | |
| MPV | fL | \$ | | \$ | | \$ | | fL | \$ | | \$ | | \$ | |
| AUXILIARY METHODS | | | | | | | | | | | | | | |
| MANUAL HCT | % | 15.3 | ± 1.5 | 31.0 | ± 2.5 | 40.1 | ± 3.5 | L/L | 0.153 | ± 0.015 | 0.310 | ± 0.025 | 0.401 | ± 0.035 |

FOOTNOTES

ENGLISH


§ The data required to establish the means and acceptable ranges for this assay were not obtained due to limited assignment participation. If your facility is interested in participating in the Value Assignment Program for this assay, please contact your local Bio-Rad office.

❖ **INTERNATIONAL USE ONLY** - The following section contains data for methods that are not available for diagnostic use in the United States.

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BIO-RAD

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