Leukocyte Reagent Kit
MD-101101

Intended Use
For the in vitro quantitative measurement of leukocyte esterase activity in urine.
NOT FOR USE IN UNPROFESSIONAL SETTINGS.

Summary and Principle
Testing leukocyte esterase (LE) activity in urine is a crucial component of urinalysis used to screen for urinary tract infections (UTIs)[1] and detect the presence of inflammatory cells, primarily neutrophils, in the urinary tract.[2] Leukocyte esterase is an enzyme released by neutrophils and other leukocytes present in urine. It serves as a surrogate for pyuria, signaling leukocyte activity even when cells are degraded or not visible in microscopy. It offers strong sensitivity (50–75%) and negative predictive value (NPV) (~95–99%), making it an effective test for ruling out infection when the result is negative.[2] A positive LE test is not specific for UTI, as sterile pyuria can occur in conditions such as interstitial nephritis, bladder malignancy, or contamination from vaginal leukocytes.[3] A positive LE, particularly alongside nitrite positivity and relevant symptoms, strongly supports UTI diagnosis and may prompt timely antibiotic therapy.

Reagents
Reagents are in ready to use format.
Reagent 1: 0.05 – 0.5 mmol/L indoxyl ester, surfactant, preservative, phosphate buffer (pH 6.5 – 7.0).
Reagent 2: 0.1 – 1.0 mmol/L diazonium salt, surfactant, preservative in phosphate buffer (pH 6.5 – 7.0).

Reagent Stability and Storage
Reagents are ready for use. Supplied reagent is stable at 2-8°C until expiry date. Stability claims are based on real-time studies. Manufacturer studies have shown that reagents are stable for 30 days once placed in the refrigerated reagent carousel (2-10°C), however reagent stability may vary based on individual laboratory conditions. Evidence of cloudiness or particulate material in solution is cause to discard.

Cautions
MISSION Leukocyte Kit is For Laboratory Use Only. May be harmful if inhaled or swallowed. Do not pipette by mouth. Avoid contact with skin and eyes. In case of contact, flush area with water. Seek immediate medical attention for eyes.

Instrumentation
MISSION Leukocyte Kit are for use on Mission Diagnostics Affirm C200 [1]and Beckman AU680 Analyzers. Refer to instrument procedure instructions in the instrument manual provided with the specific analyzer.

Specimen Collection and Handling
Proper collection and storage of urine are essential for accurate urine leukocyte esterase activity testing, as enzyme activity can degrade over time or under improper conditions. Collection: use a clean, dry, sterile container (plastic or glass). Storage: Room temperature (20–25°C) stable for <2 hours. Refrigerated at 2–8°C samples are stable for up to 24 hours.

Quality Control
Store and handle reagents properly before and during use. Every laboratory should establish its own test requirements using controls and calibrators. MISSION Diagnostics provides Quality Calibrators to meet your program needs and which conform to NLCP Guidelines[4]:

MD-101201 – Leukocyte Calibrator

Limitations and Interferences
False positives: Contamination (vaginal secretions, especially in females, with WBCs).
Trichomonas, Chlamydia, or other non-bacterial infections.
Oxidizing agents in urine (e.g., bleach contamination).
Highly alkaline urine (pH > 9).
Certain drugs (e.g., tetracyclines, clavulanic acid).
False negatives:
Dilute urine (low WBC concentration).
Antibiotics or antiseptics (may kill leukocytes or suppress esterase activity).
Presence of lymphocytes instead of neutrophils (e.g., in tuberculosis or interstitial nephritis).

Typical Performance Characteristics
The following performance data was obtained using the Affirm C200 and Beckman AU680 Analyzers. Other instruments may yield different performance data.

[1] Also known as Zybio EXC200 Analyzer

Distributed by: Mission Diagnostics LLC, 1 Burton Dr., Meridith, NH 03246
Manufactured by: Diamond Diagnostics Inc., 333 Fiske St., Holliston, MA 01746
Technical Assistance Call: 1.508.429.0450
Email: support@diamonddiagnostics.com

Linearity

The following results were obtained on an Affirm C200 and Beckman AU680 Analyzers using the MISSION Leukocyte Reagent Kit on samples containing 20, 40, 50, 75, and 100 EU/L substrate. The table below includes mean, standard deviation (SD) and Coefficient of Variation (CV) for each value.

Mean (EU/L)	SD	CV%
23.220	0.226	1.0
33.080	0.227	0.8
44.800	0.485	1.1
77.580	0.466	0.6
100.620	0.926	0.9

Precision

Studies performed on Affirm C200 and Beckman AU680 Analyzers. The precision of the assay was evaluated following a modification of NCCLS protocol EPT-T2. The within-run precision data was obtained by running two samples in replicates of 20 on the same day. The run-to-run data was obtained by running two samples in replicates over a five-day period.

Within-Run			Run-to-Run		
Mean (EU/L)	**SD**	**CV%**	**Mean** (EU/L)	**SD**	**CV%**
54.44	0.39	0.7	53.86	0.87	1.6
224.40	1.26	0.6	212.20	9.51	4.5

Analytical Specificity

Cross contamination studies have not been performed on Affirm C200 and Beckman AU680 Analyzers. Certain reagent/ instrument combinations used in sequence with this assay may interfere with reagent performance and test results. The existence of, or effects of, any potential cross contamination issues are unknown.

Test Conditions

For the data presented in this insert, studies using this reagent were performed on Affirm C200 and Beckman AU680 Analyzers using the parameters listed below.

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. Under typical operating conditions manufacturer calibration stability studies have shown the calibration curve will be stable for at least 14 days.

Method Parameters

Analyzer Specific Settings

Method type:	Endpoint
Slope:	positive
Units	EU/L
DOM wavelength	578
SUB wavelength	800
Sample volume	40
R1 volume	100
R2 volume	100
Blank rxn read (cycles)	n/a
Sample rxn read (cycles)	48 - 50

Calibration Settings

Calibration Type	Linear
Reagent Blank required	No
Calibrator 1	20
Calibrator 2	50
Calibrator 3	100

Analytical Measuring Range (AMR)

Range: (low)	20
Range: (high)	300

BIBLIOGRAPHY

1. Simerville JA, Maxted WC, Pahira JJ. *Urinalysis: a comprehensive review*. Am Fam Physician. 2005 Mar 15;71(6):1153–62.
2. Fogazzi GB, *Urinalysis: core knowledge*. Kidney Int. 2005;67(4):1616–1623.3. Medscape: *Renal Glucosuria.* *https://emedicine.medscape.com/article/983678-overview*
3. Reliability of dipstick assay in predicting urinary tract infection. 10.4103/2249-4863.154672
4. National Laboratory Certification Program. General Laboratory Inspection Checklist / Report. OMB No. 0930-0158. November, 2002

Distributed by: Mission Diagnostics LLC, 1 Burton Dr., Meridith, NH 03246
Manufactured by: Diamond Diagnostics Inc., 333 Fiske St., Holliston, MA 01746
Technical Assistance Call: 1.508.429.0450
Email: support@diamonddiagnostics.com