pH REAGENT KIT
MD-101105

Intended Use
For the determination of pH in urine.
NOT FOR USE IN UNPROFESSIONAL SETTINGS.

Summary and Principle
MISSION pH Kit is for use on AFFIRM automated analyzer to determine the pH of urine. Urine pH can reflect the body's overall metabolic state. A shift in pH can indicate issues like kidney problems, metabolic disorders, or dehydration. For instance, acidic urine can lead to uric acid or cystine stones, while alkaline urine favors calcium phosphate stones. A diet high in proteins (acidic) or vegetables (alkaline) can affect urine pH. Monitoring urine pH helps assess the impact of dietary habits on health. Urinary tract infections (UTIs) can alter urine pH, typically making it more alkaline[1]. This information can help guide treatment. Certain medications (e.g., diuretics or drugs for kidney diseases) can influence urine pH. Measuring it ensures appropriate drug efficacy and adjustments if needed[2]. The kidneys help regulate the body's acid-base balance. Urine pH measurement helps assess how well the kidneys are performing this function, which is important for overall metabolic health.

MISSION pH Kit contains indicators that react with the specimen to yield a change in absorbance (based upon the hydrogen ion concentration) which is read spectrophotometrically at 546 nm. All abnormal results should be checked by an alternative (pH meter) method.

Reagents
Reagents are packaged in ready-to-use form. No preparation is required.
MISSION pH Kit reagent contains indicators, activators, surfactants and buffers.

Reagents Stability and Storage
Unopened and open reagents are stable until expiration date when stored tightly capped at 2-8°C. It is recommended to cap on-board reagents when not in use.

Cautions
MISSION pH 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 pH Kit 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
Use clean plastic or glass containers to collect urine specimens. Protect sample from heat and light. Testing may be performed on samples at room temperature and samples may be stored refrigerated at 2-10°C. Handle all urine samples as if potentially infectious.

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 Calibrators to meet your program needs and which conform to NLCP Guidelines[3]:

MD-101205.01 – pH Calibrator 3.0
MD-101205.02 – pH Calibrator 11.0

Specificity, Limitations, and Interferences
Urine pH reflects the acidity or alkalinity of the urine and can be influenced by diet, medications, renal function, and systemic acid-base status. Urine pH can change rapidly after collection due to bacterial overgrowth, loss of CO_2, metabolic changes if refrigerated too long.

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

Linearity
The following results were obtained on an Affirm C200 and Beckman AU680 Analyzers using the MISSION pH Kit on samples with pH: 3.0, 4.5, 9.0, 10.0 and 11.0. The table below includes mean, standard deviation (SD) and Coefficient of Variation (CV) for each value.

Mean	SD	CV%
3.016	0.011	0.4
4.830	0.000	0.0
9.498	0.008	0.1
10.192	0.013	0.1
10.946	0.015	0.1

[1] Also known as Zybio EXC200 Analyzer

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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	**SD**	**CV%**	**Mean**	**SD**	**CV%**
5.263	0.009	0.2	6.095	0.184	3.0
6.836	0.018	0.3	7.544	0.175	2.3

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	pH units
DOM wavelength	546
SUB wavelength	800
Sample volume	10
R1 volume	125
R2 volume	-
Blank rxn read (cycles)	7 - 9
Sample rxn read (cycles)	16 - 20

Calibration Settings

Calibration Type	Linear
Reagent Blank required	No
Calibrator 1	3
Calibrator 2	11

Analytical Measuring Range (AMR)

Range: (low)	3
Range: (high)	11

BIBLIOGRAPHY
1. Alkaline Urine: A Cause for Urinary Tract Infection Recurrence. 2019 Oct 23;6(Suppl 2):S535. doi: 10.1093/ofid/ofz360.1330
2. Furosemide-induced urinary acidification is caused by pronounced H+ secretion in the thick ascending limb. https://doi.org/10.1152/ajprenal.00154.2015
3. National Laboratory Certification Program. General Laboratory Inspection Checklist / Report. OMB No. 0930-0158. November, 2002.

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