



Automated Flow Cytometry Urine Analysis: Reassessing Evaluation of Microscopic Hematuria

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Background

The current guidelines for identifying microscopic hematuria (defined as 3 or more red blood cells/high power field) is with visual microscopy. Flow cytometry is being introduced by labs for increased accuracy, detection and efficiency. The reference ranges for these machines may not correlate with current standards. Our goal was to establish the machine's reference interval and to compare our machine's reference interval to the gold standard and whether utilizing this range would negatively impact evaluation of hematuria.

Materials/Methods

A single institution, as part of a quality assessment project, evaluated the reference range of its new automated urinalysis machine (ARKRAY Aution AU-4050).

This evaluation was prompted by a three-fold increase in the number of microscopic hematuria referrals upon adoption of flow cytometry.

A reference interval verification was run through EP Evaluator®. A proposed normal interval of 0-3 RBC/HPF (based on current guidelines threshold for microscopic hematuria) was used and 405 consecutive urine samples processed using both visual microscopy and flow cytometry. We compared the RBCs detected by each and compared the corresponding reference intervals.

After this reference interval was established a retrospective review of the evaluations for microscopic hematuria from January 2017 to September 2017 (the period where the new machine was in use but traditional standards were being used to recommend evaluation) was performed. Descriptive statistics and analysis of variance (ANOVA) were performed to evaluate the findings.

Results



ARKRAY Aution AU-4050

Results Distribution

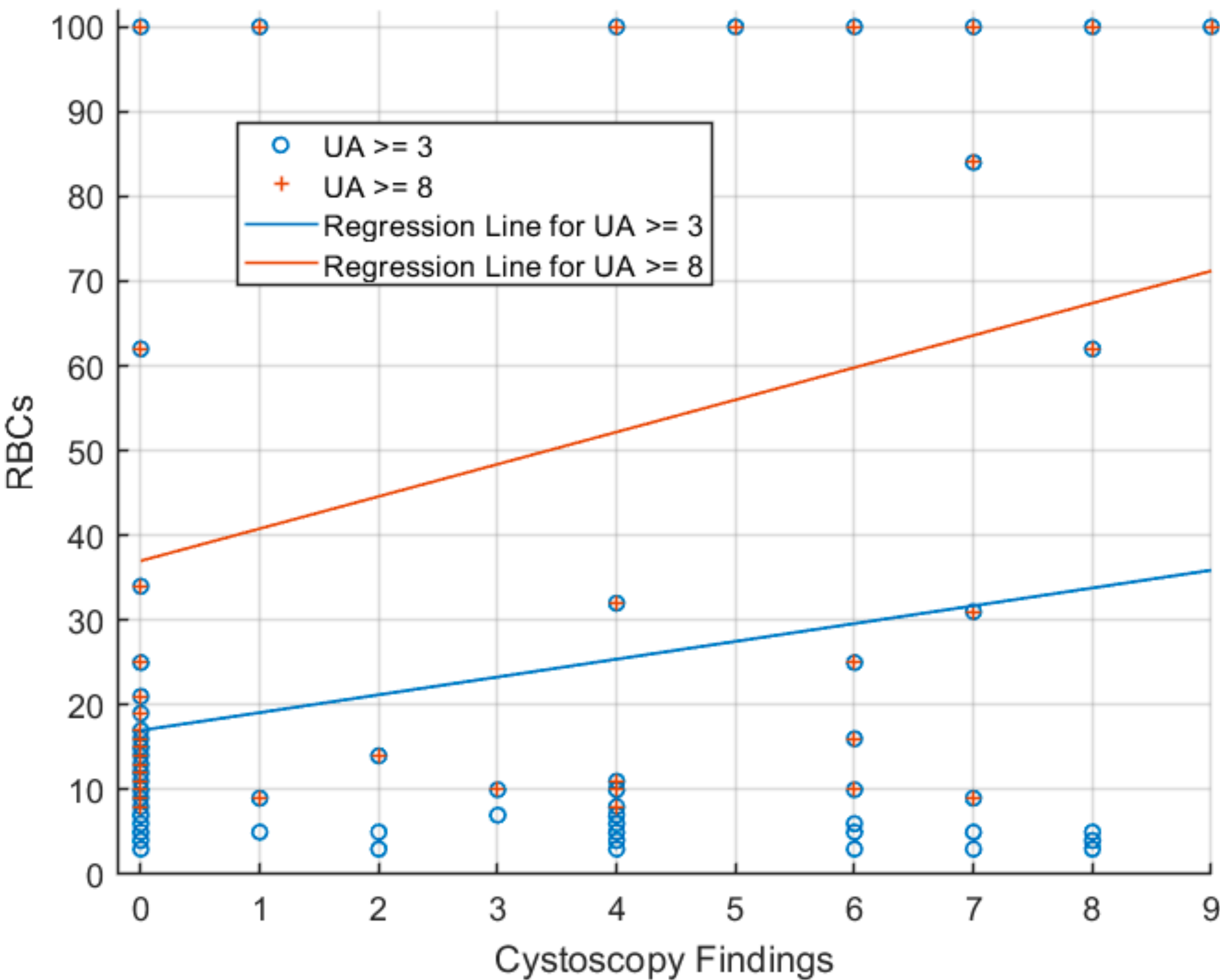
Interval	Percent	Count
< 0	0.0	0
0	8.9	36
1	22.5	91
2	19.0	77
3	16.8	68
> 3	32.8	133

Number of Samples Outside of Reference Interval

405 consecutive urine samples were evaluated with 32.8% of the samples falling outside of the reference range of 0-3 RBC/HPF. A 95% confidence interval (2.5% of upper and lower values) was used to identify the flow cytometry value that most accurately correlated with the visual microscopy reference interval of 0-3 RBC/HPF.

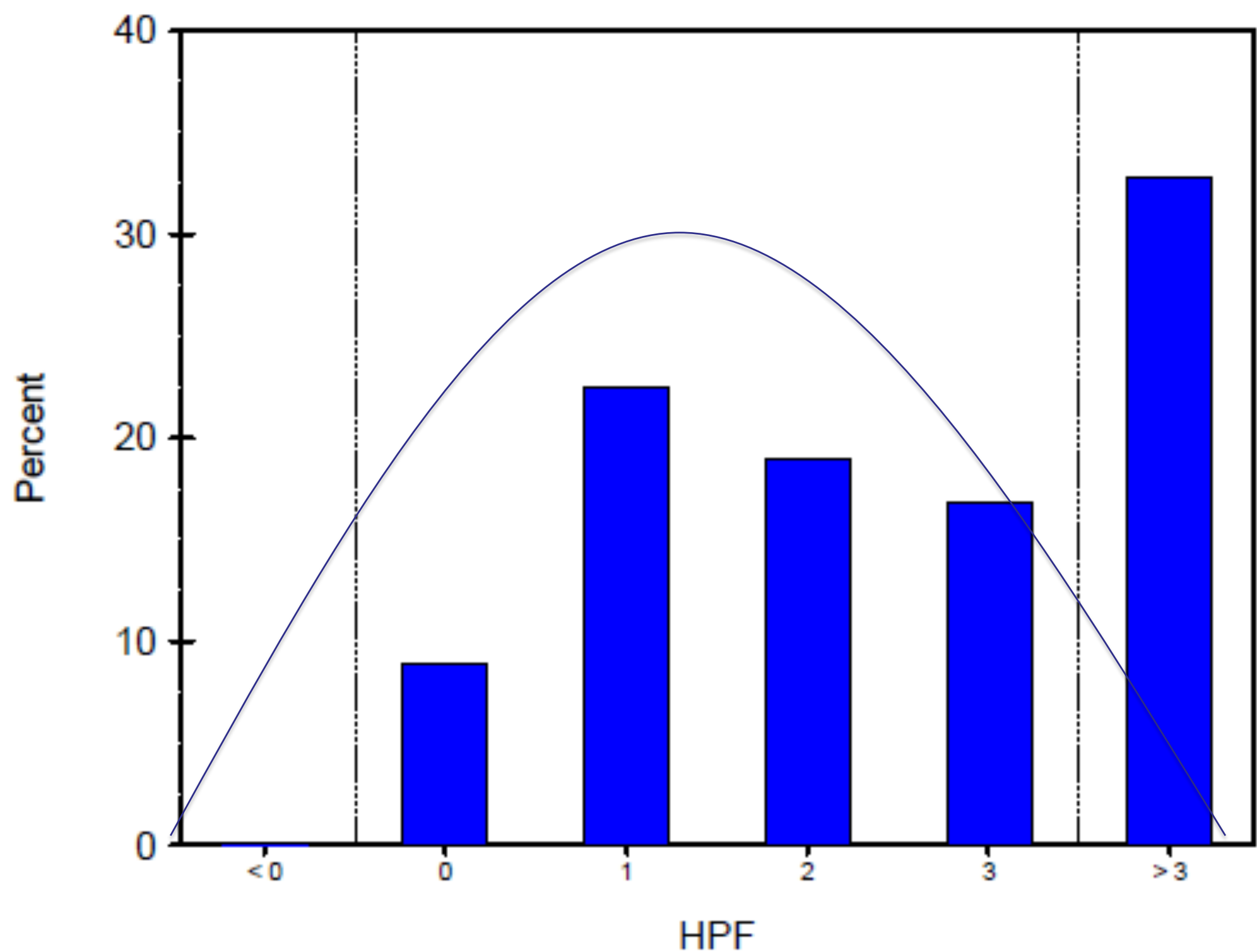
This analysis produced an accurate reference interval of 0-8 HPF for flow cytometry. 229 patients underwent evaluation of microscopic hematuria during the time period. 72% of those had a completely negative work-up. 8 of 229 had cystoscopy or CT findings consistent with a malignancy. Only one of those patients was between the traditional threshold and our new limit for evaluation. On linear regression, there was not found to be any statistical difference between the thresholds of 3 RBCs vs 8 RBCs ($p = 0.0524$).

Regression Analysis of Cystoscopy Findings Based on Number of RBCs



Cystoscopy Findings: 0-Normal 1- Bladder tumor 2- Stones 3- Diverticulum 4- BPH 5-Radiation Changes 6- Urethral stricture 7- Declined Cysto 8- Cystitis 9- AVM

Reference Interval Histogram



Discussion/Conclusions

The current guidelines for evaluation of microscopic hematuria may no longer be relevant with the use of new technology. Identifying a new reference range based on the machine is accurate and safe with regards to evaluations of hematuria

Disclosures

Views are those of the authors and not of the Army or the Department of Defense.