

DxH 520 Analyzer Is Able to Identify (flag) Specimens From Patients with Leukemia and Lymphoma with High Sensitivity

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Introduction

Laboratory diagnosis of Myeloproliferative neoplasms (MPN), Myelodysplastic syndrome (MDS), and other Leukemia and Lymphoma (L&L) relies on cytogenetic, molecular, and microscopic analysis. Use of the complete blood count (CBC) and differential parameters along with suspect flagging messages on the DxH 520 (a small bench top analyzer) can be used to identify patients who require reflex testing for L&L diagnosis.

Methods

41 Whole blood samples from patients with L&L were collected from three sites and tested on the DxH 520. Manual slide review of two 200 cell count slides was performed. The samples were de-identified and part of a larger group (Table 2) evaluated for clinical sensitivity so diagnosis was blinded at the time of testing. The analysis used both morphological (suspect flagging) and distributional anomalies (CLSI H20 A2:2007) to determine clinical sensitivity.

Conclusions

The DxH 520 analyzer is able to help identify samples from patients with L&L that need to be reflexed for manual slide differential and additional testing.

Leukemia & Lymphoma



Test	Reference	
Frequency	Positive	Nega
Positive	33	3
Negative	0	5
Total	33	8

 Table 1: 2x2 analysis of L&L samples DxH 520

vs manual differential.

SID	Diagnosis	Clinical
	Diagnosis	agreement
CLS-006	Acute Myeloid	TP
CLS-031	Chronic Myelomonocytic	TP
CLS-044	Acute Myeloid	TP
CLS-056	Acute Myeloid	TP
CLS-071	Multiple Myeloma	FP
CLS-089	Acute Myeloid	FP
CLS-092	Chronic Myeloid	TP
CLS-114	Chronic Lymphocytic	TP
CLS-148	Acute Myeloid	FP
IUH-087	Acute Lymphoblastic	TN
IUH-091	Acute Lymphoblastic	TP
IUH-094	Acute Lymphoblastic	TP
IUH-098	Acute Lymphoblastic	TP
IUH-099	Acute Lymphoblastic	TP
IUH-101	Acute Lymphoblastic	TP
IUH-102	Acute Lymphoblastic	TP
IUH-108	Acute Myeloid	TP
IUH-112	Acute Myeloid	TP
IUH-113	Acute Myeloid	TP
IUH-126	Acute Lymphoblastic	TP

When a clinical sensitivity analysis was performed comparing the 41 L&L samples to manual microscopy there were no false negative samples. There were 3 false positive samples where the DxH 520 indicated slide review when microscopy did not reveal an abnormality. The overall clinical sensitivity included 424 samples and showed a false negative rate of 13.5% and a false positive rate of 31.3%

		All Samples Enrolle		
	Test	Refere	٢	
ative	Frequency	Positive		
3	Positive	193		
5	Negative	30		
3	Total	223		
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Table 2: 2x2 analysis of all samples from three sites. DxH 520 vs manual differential. The DxH 520 showed overall sensitivity of 0.865 and specificity of 0.687.

SID	Diagnosis	Clinical agreement
IUH-127	Chronic Lymphocytic	TP
IUH-145	Other Cancer	TP
IUH-158	Acute Myeloid	TP
IUH-162	Acute Lymphoblastic	TP
IUH-163	Acute Myeloid	TP
IUH-166	Acute Lymphoblastic	TP
IUH-178	Acute Lymphoblastic	TP
IUH-182	Acute Lymphoblastic	TP
IUH-187	Acute Lymphoblastic	TP
IUH-188	Acute Lymphoblastic	TP
IUH-191	Acute Lymphoblastic	TN
LHS-035	Acute Lymphoblastic	TP
LHS-040	Chronic Myeloid	TN
LHS-052	Acute Myeloid	TP
LHS-058	Acute Myeloid	TP
LHS-079	Acute Lymphoblastic	TP
LHS-080	Other Leukemia	TN
LHS-088	Acute Lymphoblastic	TP
LHS-095	Acute Lymphoblastic	TP
LHS-117	Acute Lymphoblastic	TP
LHS-128	Chronic Myeloid	TN

Table3: Diagnosis and Agreement Table by Sample.

Results





