Fluorobot, the World's first robotic, LED based, smear microscope for tuberculosis screening.

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Introduction

With 9 Millions of new cases annually and almost 1.5 Million of deaths, Tuberculosis (TB) is still a leading mortality factor. Manual sputum smear microscopy is the most widely used screening method for the diagnostic of TB in suspected patients, as it is the most affordable and often the only accessible method in low resource environments. This results over 87 million tests in 2014, with WHO estimations of 200 million determinations to be reached by 2020.

Method

ConsultAsk developed an automated microscope prototype for TB smear reading. Based on fluorescence, this instrument can read 20 slides per hour. Standardization, reproducibility, image storage and laboratory throughput improvement are the expected benefits of the instrument.

The prototype has been evaluated in a field study performed at the Gheskio centers in Haïti.

•369 samples, 119 negative and 250 positive, were selected using GeneXpert (Cepheid) or culture (liquid and solid), and tested by the automate and human reading.

•Fluorobot performances were compared to human reading and culture.

Study Protocol

Results

Table 1: Smear results according to WHO classification.
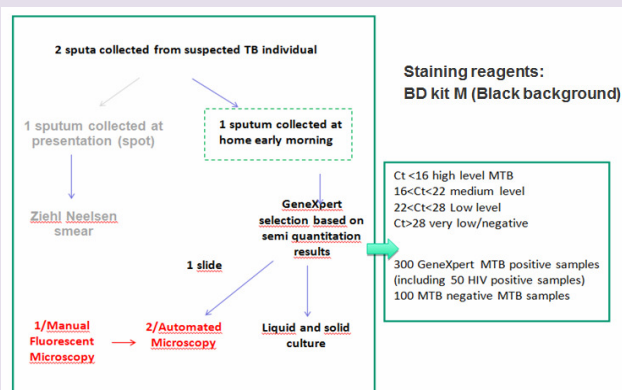
	CULTURE			
	Pos		Neg	
	Human Reading	Fluorobot	Human Reading	Fluorobot
3+	83	75	0	0
2+	54	43	2	1
1+	44	39	2	1
Scanty	42	46	33	38
Neg	27	47	82	79

		Human reading	
		Pos	Neg
Fluorobot	Pos	216	27
	Neg	44	82
		260	109

Table 2: Method comparison with Scanty specimen considered as positive (WHO recommendation)

	Performances vs Culture			
	Sensi. (IC 95%)	Specif. (IC 95%)	NPV (IC 95%)	PPV (IC 95%)
Human Reading	0.892 [0.847-0.928]	0.689 [0.598-0.771]	0.752 [0.660-0.830]	0.858 [0.809-0.898]
Fluorobot	0.812 [0.758-0.859]	0.664 [0.572-0.748]	0.627 [0.536-0.711]	0.835 [0.783-0.880]

Table 3: Performances with Scanty specimen considered as positives .

	Performances vs Culture			
	Sensi. (IC 95%)	Specif. (IC 95%)	NPV (IC 95%)	PPV (IC 95%)
Human Reading	0.834 [0.773 - 0.884]	0.984 [0.912–1.000]	0.659 [0.553-0.755]	0.994 [0.965–1.000]
Fluorobot	0.877 [0.821-0.920]	0.967 [0.887-0.996]	0.720 [0.609-0.813]	0.988 [0.957-0.999]

Table 4: Performances with Scanty specimen considered as indeterminate and excluded from the calculation (20%): to be re-analyzed or re-tested.

Conclusions

❖The automated fluorescent microscope, Fluorobot, shows a very good concordance with human reading for TB smear analysis.

❖Even if 20% of the samples requires a new reading of the slide or shipment of the image to a specialist, Fluorobot can save 80% of the routine work in a TB microscopic center.

❖After slight improvements of the prototype, a multi-center study will be performed to confirm these promising results.