Medical Diagnostic Laboratories

Comparison of Multiple Assay Systems for the Detection of Gynecological Pathogens

Chlamydia trachomatis

Test	N[a]	Prevalence (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	References
PCR	1000	12.9	98	100	100	100	(1)
Amplicor	2254	7.5*	96.9	98.6	84.9*	99.7*	(2, 3)
Aptima Combo 2	1389	15.0	94.2	97.6	87.4	99.0	(4)
BD Probe Tec	1419	9.9	98.7	97.8	84.8	99.1	(5)
GEN-PROBE (Pace 2)	940	3.9	75.5	97.0	50.5	99.0	(6)

* *calculated data*

Human Papillomavirus (HPV)

Test	Speicmen	Prevalence (%)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	References
PCR	**Total (n = 596)**	37.8	100	100	100	100	(7, 8)
	Normal Cytology	25.1					
	ASCUS	55.9					
	Low Grade SIL	68.7					
	High Grade SIL	81.6					
	Squamous cervical carcinomas	100					
HC-II	Total (n = 596)	32.9	78.7	89.2	78.12	89.52	(7, 8)
	Normal Cytology	19.5 (14.3 HR)	70.0	80.8	46.90	91.75	
	ASCUS	52.9 (41.1)	87.3	97.5	97.51	87.24	
	Low Grade SIL	64.5 (59.4)			98.45	80.86	
	High Grade SIL	81.6			99.36	63.39	
	Squamous cervical carcinomas	100			100	-	

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References:

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6. Blanding J, Hirsch L, Stranton N, et al. 1993. Comparison of the Clearview Chlamydia, the PACE 2 assay, and culture for detection of *Chlamydia trachomatis* from cervical specimens in a low-prevalence population. *J Clin Microbiol* 31:1622-1625.
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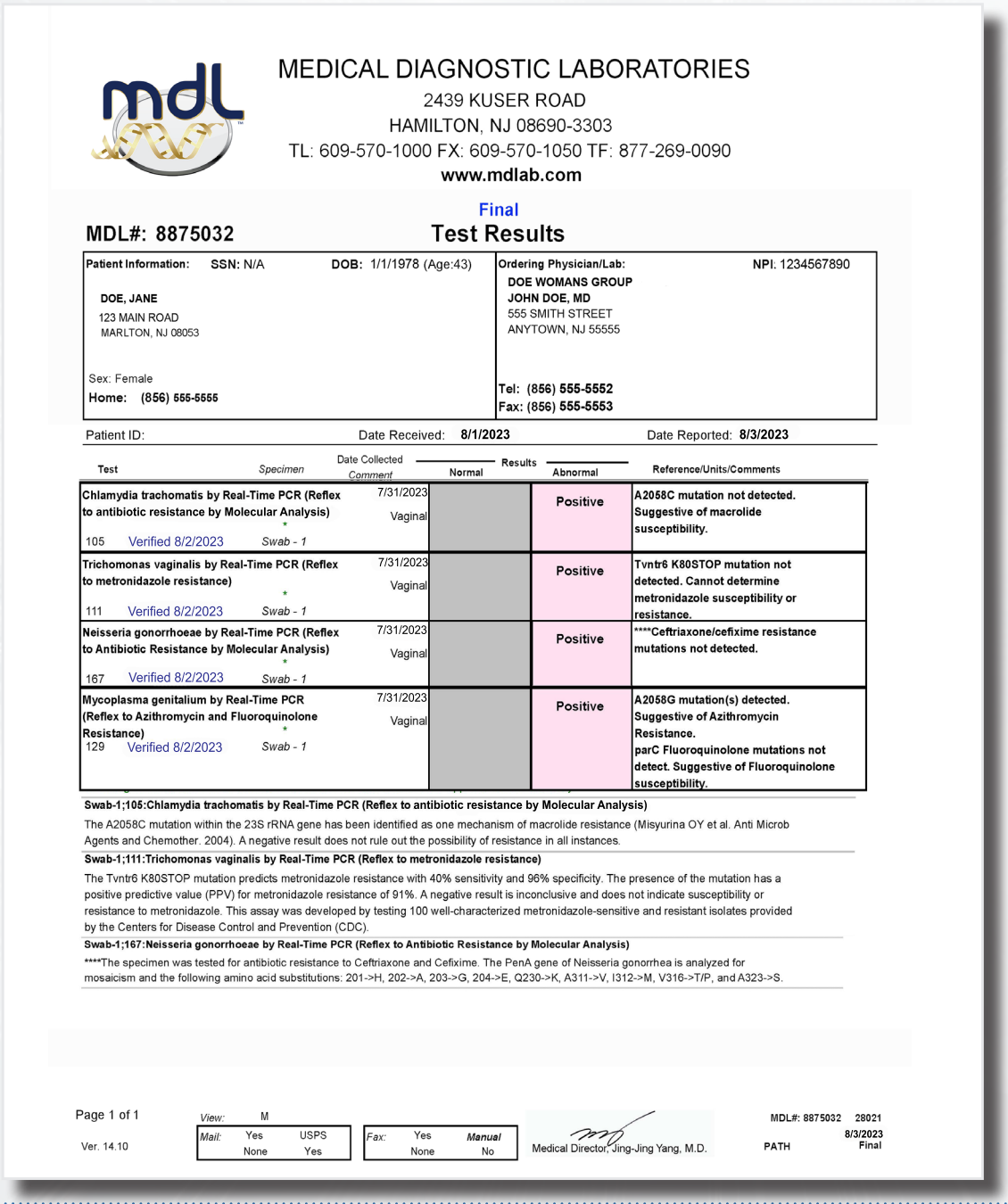
8. Lie AK, Skjeldestad FE, Hagen B, et al. 1997. Comparison of light microscopy, in situ hybridization and polymerase chain reaction of human papillomavirus in histological tissue of cervical intraepithelial neoplasia *APMIS* 105:115-120.



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Final

MDL#: 8875032 **Test Results**

Patient Information:	SSN: N/A	DOB: 1/1/1978 (Age:43)	Ordering Physician/Lab:	NPI: 1234567890
DOE, JANE 123 MAIN ROAD MARLTON, NJ 08053 Sex: Female Home: (856) 555-5555			DOE WOMANS GROUP JOHN DOE, MD 555 SMITH STREET ANYTOWN, NJ 55555 Tel: (856) 555-5552 Fax: (856) 555-5553	

Patient ID: Date Received: **8/1/2023** Date Reported: **8/3/2023**

Test	Specimen	Date Collected / Comment	Results: Normal	Results: Abnormal	Reference/Units/Comments
Chlamydia trachomatis by Real-Time PCR (Reflex to antibiotic resistance by Molecular Analysis) * 105 Verified 8/2/2023	Swab - 1	7/31/2023 Vaginal		Positive	A2058C mutation not detected. Suggestive of macrolide susceptibility.
Trichomonas vaginalis by Real-Time PCR (Reflex to metronidazole resistance) * 111 Verified 8/2/2023	Swab - 1	7/31/2023 Vaginal		Positive	Tvntr6 K80STOP mutation not detected. Cannot determine metronidazole susceptibility or resistance.
Neisseria gonorrhoeae by Real-Time PCR (Reflex to Antibiotic Resistance by Molecular Analysis) * 167 Verified 8/2/2023	Swab - 1	7/31/2023 Vaginal		Positive	****Ceftriaxone/cefixime resistance mutations not detected.
Mycoplasma genitalium by Real-Time PCR (Reflex to Azithromycin and Fluoroquinolone Resistance) * 129 Verified 8/2/2023	Swab - 1	7/31/2023 Vaginal		Positive	A2058G mutation(s) detected. Suggestive of Azithromycin Resistance. parC Fluoroquinolone mutations not detect. Suggestive of Fluoroquinolone susceptibility.

Swab-1;105:Chlamydia trachomatis by Real-Time PCR (Reflex to antibiotic resistance by Molecular Analysis)

The A2058C mutation within the 23S rRNA gene has been identified as one mechanism of macrolide resistance (Misyurina OY et al. Anti Microb Agents and Chemother. 2004). A negative result does not rule out the possibility of resistance in all instances.

Swab-1;111:Trichomonas vaginalis by Real-Time PCR (Reflex to metronidazole resistance)

The Tvntr6 K80STOP mutation predicts metronidazole resistance with 40% sensitivity and 96% specificity. The presence of the mutation has a positive predictive value (PPV) for metronidazole resistance of 91%. A negative result is inconclusive and does not indicate susceptibility or resistance to metronidazole. This assay was developed by testing 100 well-characterized metronidazole-sensitive and resistant isolates provided by the Centers for Disease Control and Prevention (CDC).

Swab-1;167:Neisseria gonorrhoeae by Real-Time PCR (Reflex to Antibiotic Resistance by Molecular Analysis)

****The specimen was tested for antibiotic resistance to Ceftriaxone and Cefixime. The PenA gene of Neisseria gonorrhea is analyzed for mosaicism and the following amino acid substitutions: 201->H, 202->A, 203->G, 204->E, Q230->K, A311->V, I312->M, V316->T/P, and A323->S.

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Ver. 14.10

View: M

Mail: Yes USPS / None Yes

Fax: Yes Manual / None No

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