

K936054

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**Summary of Safety and Effectiveness Information
Supporting a Substantially Equivalent Determination**

The following information as presented in the 510(k) Premarket Notification for IMx SELECT Chlamydia constitutes data supporting a substantially equivalent determination:

IMx SELECT Chlamydia is a Microparticle Enzyme Immunoassay (MEIA) for the qualitative detection of chlamydial LPS antigen and is indicated for use in testing female endocervical swab specimens, and male urethral swab specimens from symptomatic individuals to identify Chlamydia trachomatis. The IMx SELECT Chlamydia Blocking Reagent may be used to verify the chlamydial specificity of the antigen detected.

IMx SELECT Chlamydia is compared to isolation of C. trachomatis in tissue culture.

IMx SELECT Chlamydia and isolation of C. trachomatis in cell culture are substantially equivalent in that:

- a. Both are intended for the detection of C. trachomatis infection.
- b. Both are in vitro tests.

IMx SELECT Chlamydia and isolation of C. trachomatis in cell culture differ in that:

- a. IMx SELECT Chlamydia measures C. trachomatis antigen and therefore detects chlamydia which fail to grow in cell culture.
- b. IMx SELECT Chlamydia can be preformed in less than ninety minutes whereas cell culture techniques require a minimum of 48 hours before results are obtained.
- c. IMx SELECT Chlamydia specimens do not require special handling and storage procedures to retain viability.

A total of 1647 specimens were obtained from patients attending 6 different clinics, including sexually transmitted disease clinics, family planning clinics and OB/GYN clinics. The overall results, presented by symptomology and by prevalence and site, are shown in the tables below:

**IMx SELECT Chlamydia Performance versus Culture with Discordant Resolution by DFA
Summary by Symptomology**

Population By Sample Type	IMx:	Pos	Pos	Pos	Neg	Neg	Total number of Samples	% Relative Sensitivity (95% CI)	% Relative Specificity (95% CI)	% Positive Predictive Value	% Negative Predictive Value	
	Culture:	Pos	Neg	Pos	Neg	Pos						Neg
	DFA:	NA	Pos	Neg	NA	NA						NA
FEMALE: Total		134	15	14	15	982	1160	90.9 (149/164) (85.4-94.8)	98.6 (982/998) (97.7-99.3)	91.4 (149/163)	91.5 (982/997)	
FEMALE: Symptomatic		46	8	8	8	308	370	89.7 (52/59) (78.8-98.1)	99.1 (309/312) (96.0-99.3)	89.7 (52/58)	98.1 (309/312)	
FEMALE: Asymptomatic		44	5	6	8	380	450	89.1 (49/55) (77.8-95.8)	98.0 (380/388) (98.1-99.1)	98.0 (49/57)	98.0 (380/388)	
FEMALE: Other		44	4	0	3	286	337	94.1 (48/61) (83.8-98.8)	100.0 (288/288) (99.0-100.0)	100.0 (48/48)	99.0 (288/288)	
MALE: Symptomatic		88	15	4	16	388	407	83.5 (81/97) (74.6-90.3)	99.0 (388/390) (97.4-99.7)	85.3 (81/95)	99.0 (388/402)	
GRAND TOTAL		200	30	18	31	1368	1647	88.1 (230/261) (83.6-91.6)	98.7 (1368/1388) (98.0-99.2)	92.7 (230/246)	97.8 (1368/1388)	

NA is not applicable. DFA testing not performed
CI is Confidence Interval

- * Routine prenatal screen or no specific information provided
- * 23/29 culture positive, IMx negative specimens contain < 20 IFUs, 28/29 specimens have < 100 IFUs; 2 culture negative, IMx negative specimens were positive when tested by DFA.
- * Six specimens, reactive by IMx SELECT Chlamydia but negative by culture/DFA, were tested by Polymerase Chain Reaction (PCR) technology. All six specimens were PCR positive. In addition, 7 out of 16 specimens tested with the IMx SELECT Chlamydia Blocking Reagent were verified as positive for chlamydial LPS antigen.

**IMx SELECT Chlamydia Performance versus Culture with Discordant Resolution by DFA
Summary by Prevalence and Site**

Population By Sample Type	IMx:	Pos	Pos	Pos	Neg	Neg	Total number of Samples	% Relative Sensitivity (95% CI)	% Relative Specificity (95% CI)	% Prevalence	
	Culture:	Pos	Neg	Pos	Neg	Pos					Neg
	DFA:	NA	Pos	Neg	NA	NA					NA
FEMALE: Total		134	15	14	15	982	1160	90.9 (149/164) (85.4-94.8)	98.6 (982/998) (97.7-99.3)	14.1 (184/1160)	
HIGH Prevalence		95	7	6	6	481	575	94.4 (102/108) (88.3-97.9)	98.7 (481/487) (97.2-99.6)	16.8 (108/679)	
Site 1		54	3	5	3	238	304			19.7 (50/304)	
Site 1 (In-House Testing)		41	4	0	3	223	271			17.7 (48/271)	
MID Prevalence		35	6	8	8	308	447	84.3 (43/51) (71.4-93.0)	98.0 (388/396) (98.1-99.1)	11.4 (51/447)	
Site 2		5	1	2	4	140	152			8.6 (10/152)	
Site 3		30	7	6	4	248	295			13.9 (41/295)	
LOW Prevalence		4	0	0	1	193	198			3.8 (8/198)	
Site 4		3	0	0	0	63	66			4.8 (3/66)	
Site 5		1	0	0	1	70	72			2.8 (2/72)	
MALE: Total		88	15	4	16	388	407	83.5 (81/97) (74.6-90.3)	99.0 (388/390) (97.4-99.7)	10.9 (97/487)	
Site 3		39	7	2	13	238	299			10.7 (50/299)	
Site 3 (In-House Testing)		23	6	2	3	107	141			22.7 (32/141)	
Site 6		4	2	0	0	41	47			12.8 (6/47)	
GRAND TOTAL		200	30	18	31	1368	1647	88.1 (230/261) (83.6-91.6)	98.7 (1368/1388) (98.0-99.2)	15.9 (281/1647)	

In conclusion, the IMx SELECT Chlamydia Assay is substantially equivalent to the isolation of C. trachomatis in cell culture for the detection of C. trachomatis antigens in endocervical and male urethral swab specimens.

**Prepared and submitted May 7, 1996
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