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Summary of Safety and Effectiveness in Accordance with SMDA of 1990

Studies performed at LMD Laboratories compared the upgraded version of the *Cryptosporidium* Antigen Detection Assay against LMD's original version *Cryptosporidium* Antigen Detection Assay and Conventional Microscopic Exam (CME). The CME results, as well as virtually all of the samples, were obtained from Mayo Clinic. These samples are actual specimens submitted to Mayo Clinic Reference Laboratory for O&P examination.

The following results were obtained:

n=130

	Upgraded	Original
CME negative = 76	75/76 were negative	73/76 were negative
CME positive = 54	51/54 were positive	49/54 were positive
	Specificity =99%	Specificity =96%
	95% CI = 93 to 100%	95% CI = 89 to 99%
	Sensitivity = 94%	Sensitivity = 91%
	95% CI = 85 to 99%	95% CI = 80 to 97%

The studies found no cross reactivity with stools containing the following organisms: *Endolimax nana, Entamoeba histolytica, Entamoeba coli, Blastocystis hominus, Dientamoeba fragilis, Entamoeba hartmanni, Chilomastix mesnili,* rotavirus, *Giardia, Campylobacter jejuni*, pinworm, *Salmonella* sp. and white blood cells.

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