

	Radox	Radox	Radox
1) What is the name of your company's molecular diagnostic testing product?	Kearneysville, Wva (866) 472-6369; www.radox.com	Kearneysville, Wva (866) 472-6369; www.radox.com	Kearneysville, Wva (866) 472-6369; www.radox.com
2) What year did it first appear on the market?	STI multiplex array	Familial Hypercholesterolemia (FH) arrays I and II	Respiratory multiplex array
3) For what purpose, condition, or disease is the product designed?	2014	2014	2014
4) What is the specimen type (eg, serum, cultured cell lines, tissue, etc)?	Simultaneous detection of 10 sexually transmitted infections from a single patient sample	Simultaneous detection of 40 FH-causing mutations within the LDLR, ApoB, and PCSK9 genes in cases of suspected familial hypercholesterolemia (FH)	Simultaneous detection of 22 viral and bacterial respiratory pathogens
5) Please note the platforms used (eg, bead arrays, microarrays, PCR, RT-PCR, etc).	Genomic DNA is extracted from urine or urogenital swab samples.	Genomic DNA is extracted from a blood sample.	RNA and DNA are extracted from bronchoalveolar lavage, nasopharyngeal swab, sputum, or saliva samples.
6) What is the turnaround time for test results, and how much tech time is required per assay setup?	The array utilizes Biochip Array Technology, a unique multiplexing method that combines multiplex PCR, probe hybridization, and chemiluminescence detection.	The array utilizes Biochip Array Technology, a unique multiplexing method that combines multiplex PCR, probe hybridization, and chemiluminescence detection.	The array utilizes Biochip Array Technology, a unique multiplexing method that combines multiplex PCR, probe hybridization, and chemiluminescence detection.
7) How many channels/specimen samples are tested per run (per plate, etc)?	Turnaround time from sample to result is 6 hours.	Turnaround time from sample to result is ~3 hours.	Turnaround time from sample to result is 6 hours.
8) Is this an automated or manual system, and what are the space/environmental requirements?	One biochip is required per patient sample; one negative control is required per run; 54 biochips per carrier.	One biochip is required per patient sample; one negative control is required per run; 108 biochips per carrier.	One biochip is required per patient sample; one negative control is required per run; 108 biochips per carrier.
9) Is the product FDA-cleared/pending/approved?	The Evidence Investigator is a semiautomated, benchtop biochip analyzer that offers complete patient profiling.	The Evidence Investigator is a semiautomated, benchtop biochip analyzer that offers complete patient profiling.	The Evidence Investigator is a semiautomated, benchtop biochip analyzer that offers complete patient profiling.
10) Can the system be incorporated in the LIS?	FDA approval is pending.	FDA approval is pending.	FDA approval is pending.
11) Is this unit acquired by purchase, lease, or reagent rental, and what is the cost per assay?	The Evidence Investigator is LIMS-integrated for convenient reporting.	The Evidence Investigator is LIMS-integrated for convenient reporting.	The Evidence Investigator is LIMS-integrated for convenient reporting.
12) How is QC handled? Is it internal, external, or both? Is this part of the reagent supplied, or is an external source required?	The unit can be acquired by capital purchase, lease, and reagent rental routes. The full FH mutation panel has 40 targets, divided into 2 x 20 mutation kits.	The unit can be acquired by capital purchase, lease, and reagent rental routes. The full FH mutation panel has 40 targets, divided into 2 x 20 mutation kits.	The unit can be acquired by capital purchase, lease, and reagent rental routes.
	Biochip QC is handled internally and externally. Reference and correction spots at the same location on each chip ensure that the CCD camera within the Evidence Investigator is properly aligned. Each run has a negative control, and there is also an internal extraction control.	Biochip QC is handled internally and externally. Reference and correction spots at the same location on each chip ensure that the CCD camera within the Evidence Investigator is properly aligned. Each run has a negative control, and there is also an internal extraction control.	Biochip QC is handled internally and externally. Reference and correction spots at the same location on each chip ensure that the CCD camera within the Evidence Investigator is properly aligned. Each run has a negative control, and there is also an internal extraction control.