

Crystal[®] V_C

Test Procedure



Take solid / liquid Stool sample in to sample processing vial containing reaction buffer.

Recap sample processing vial tightly and shake it to mix the content properly.

Break the outer end of the sampling stick.

Dispense 4 drops of processed sample in test tube. Place the Test Dipstick vertically into the test tube.

Read the results after 15-20 minutes

Note : For confirmation, mix sample with Alkaline Peptone Water (APW), incubate it at +20 °C to +40 °C for 4 hours. Use it as a sample.

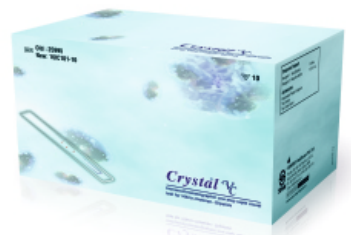
Interpretation of Results

Note: Results should not be read beyond 30 minutes

Result Type	Band Pattern	Interpretation
Negative	Only 1 band at C	Only 1 band at C
	2 bands at C & T1	Positive for LPS Ag. of <i>V. cholerae</i> O139
	2 bands at C & T2	Positive for LPS Ag. of <i>V. cholerae</i> O1
	3 bands at C, T1 & T2	Positive for LPS Ag. of <i>V. cholerae</i> O139 & O1
Invalid	Only 1 band at T1	Invalid
	Only 1 band at T2	Invalid
	2 bands at T1 & T2	Invalid
	No band	Invalid

Ordering Information

Product	Code No.	Pack size
Crystal [®] V _C	16IC101-05	05 Tests
	16IC101-10	10 Tests
	16IC101-50	50 Tests
APW vials	99RG104-10	Available separately



THE MANUFACTURING SITE'S QMS IS CERTIFIED FOR ISO 13485:2003, ISO 9001:2008



Rapid visual immunochromatographic test for qualitative and **Differential** detection of *V. cholerae* in stool

Fact File

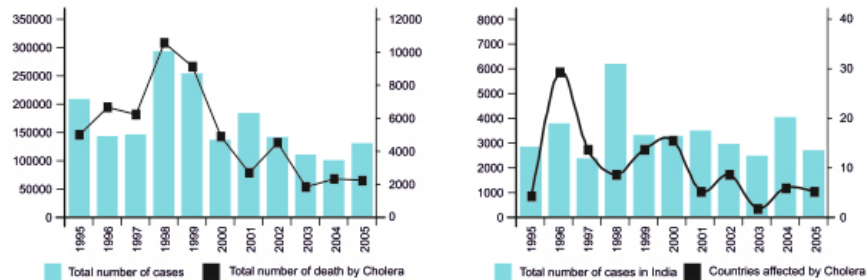
More than 60 (mainly resource poor and developing) countries affected worldwide*. More than 1.75 million cases and >56,000 deaths reported by WHO in last 12 years*. >45,000 Cholera cases are reported in India by WHO*. Average case fatality rate of cholera is >3.0 % worldwide.*

The true burden of cholera is probably several million cases in Asia and Africa with fewer cases in Latin America and an annual mortality of at least 40,000 to 100,000.**

In India, West Bengal is considered as "homeland of cholera" with frequent localized outbreaks being reported. Outbreaks of cholera including major epidemics have occurred from time to time at various places in India, like Chandigarh, Delhi, Mumbai & West Bengal.

* Weekly epidemiological report 1995 to 2006, <http://www.who.int/wer>

** Indian J Med Res 125, May 2007, pp 612-614



Diagnosis Of Cholera

Cholera is most feared stigmatized diarrhoeal disease which remains a challenge to modern medical world. Currently available diagnostic methods are culture methods, microscopic examination and direct antigen detection methods.

Culture method remains a gold standard for diagnosis of cholera. However unavailability of specialized functional laboratory, long procedure time and high cost of cultural method make it unsuitable for routine screening and field use especially in poor and developing countries where prevalence of cholera is highest.

Microscopic observation of organism's characteristic motility from stool sample by direct bright or dark field microscope is popular and widely used method. However it requires careful transportation of the sample, good clinical laboratory and expertise in microscopic examination of material.

Rapid Immunochromatography test for direct antigen detection from stool is easy to use, time saving and does not require any special transport media & sophisticated instrument. The simplicity and efficacy of rapid test improve patient's care and epidemiological surveillance, even in the remotest regions.

Crystal[®] VC detects the variants of *V. cholerae* O1 'E1 Tor hybrid' frequently observed in India. Test is developed under technical collaboration with Institute Pasteur, Paris.

Salient Features



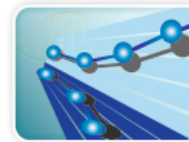
Non instrumental visual qualitative immunoassay with inbuilt control band to validate successful completion of assay procedure.



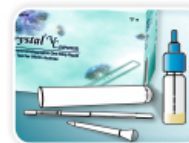
Simple, convenient and rapid assay procedure of 15 minutes. Convenient for Point of Care Testing as well as epidemiological studies in remote areas.



Two separate bands for simultaneous and differential detection of *V. cholerae* O139 and O1 in a single test strip.



High sensitivity and specificity for *V. cholerae* O139 and O1 ensures high reliability of results.



All components and accessories required to perform test are included in the kit. Individual pre-filled sample processing vial provided to process each sample.

Performance*

	<i>V. cholerae</i> O1	<i>V. cholerae</i> O139
Sensitivity	88 - 100%	99%
Specificity	61 - 87.3%	96%

*Data on Arkray file.