Merck's Lateral Flow Tests
For the rapid detection of pathogens

Food-mediated infections are a matter of worldwide concern that is increasing day by day. A broad spectrum of analytical measures is required to comply with the regulatory requirements. With its range of rapid tests for the detection of Salmonellae, Listeria, Campylobacter, E. coli 0157 and Verotoxin-producing strains of E.coli (verotoxins VT1 and VT2), Merck offers reliable and cost-effective tools for the determination of these most relevant pathogens.

All of the above tests are based on the immunoflow principle (gold-labeled immunosorbent assay) which is identical to the widely accepted "Pregnancy test" technology. Through the use of high-quality, gold-labeled antibodies, these tests match conventional methods as regards sensitivity and specificity. However, the results are obtained by far more rapidly: unambiguous results are available within 20 minutes in all of these five tests.

Thanks to specifically adapted enrichment media you no longer need to spare time for preparatory measures. They also help you to obtain precise test results. Making use of our many years of experience with the classical enrichment media, we at Merck have exactly adapted the various broths.
Thus, you obtain the same level of reliability and safety with each and every test.

The accuracy, reliability and performance of Merck's Lateral Flow Tests has been demonstrated and confirmed by different studies whose main features are summarized below.

Evaluation of the Duopath® Verotoxin Test for Detection of Shiga Toxins in Stools

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Poster ASM Meeting , Washington D.C, May 2003

Both Duopath® Verotoxin and Premier EHEC gave comparable results. The use of Duopath® Verotoxin enables the laboratory to determine the presence of STEC in 24 h after plating onto SMAC plates without the use of further confirmatory tests circumventing the need for a reference laboratory confirmation.
The results of Duopath® Verotoxin are easy to interpret and the methodology is simple, and although its assay was originally designed for use with food products, we believe it has a great potential for clinical applications as well.
Test results are easy to interpret, and the methodology is simple enough that laboratory personnel at all levels can perform the test.

Independent Evaluation of the Merck Duopath® Verotoxin *G*old *L*abeled *I*mmuno*S*orbent *A*ssay (GLISA) Method Compared to Oxoid VTEC-RPLA for the Detection of VT1 and VT2 in Pasteurized Whole Milk

Conclusions in the final report of the independent US-lab about the trials to receive the AOAC approval for Duopath® Verotoxin:

- The Merck Duopath® Verotoxins *G*old *L*abeled *I*mmuno*S*orbent *A*ssay (GLISA) assay can identify VT1 and VT2 48 hours faster than the Oxoid VTEC-RPLA method.
- There appears to be 100% correlation between the results of the Merck Duopath® Verotoxin GLISA and the Oxoid VTEC-RPLA methods.
- There were no false negative or false positive results.
- There were no ambiguous results.
- The Merck Duopath® Verotoxins test is a very user friendly assay. Compared to the Oxoid Latex test, the Merck Duopath® Verotoxins test requires less time to prepare the enriched sample, less time to add the samples to the test, the results were obtained faster (20 min versus 24 hrs) and the results are much easier interpret.

SINGLEPATH® *E. COLI* O157 AND DUOPATH® VEROTOXINS:

EVALUATION OF IMPROVED IMMUNOCHROMATOGRAPHIC RAPID TESTS FOR THE DETECTION OF VEROCYTOTOXIGENIC *E. COLI* O157 AND NON-O157 STRAINS IN FOOD

BÜLTE[1], M., A. STAHL[1], M. GOLL[1], B. KUNZ[2] and A. BUBERT[2]

Poster VTEC Conference , Edinburgh , June 2003

The overall sensitivity of Singlepath® in these trials was 100% using mTSB+N. Artificially contaminated samples enriched in mEC-broth showed a sensitivity of 97,4%. With REVEAL the sensitivity was 95,9 % for both enrichment broths. The specifity was found to be as well as 100%. Singlepath® E coli O157 and Duopath® Verotoxin tests can be recommended as easy-to-handle devices for routine testing of foods.

Independent Evaluation of the Merck Singlepath EC0157 *G*old *L*abeled *I*mmuno*S*orbent *A*ssay (GLISA) Method Compared to the

Standard Method for the Detection of E.coli 0157:H7 in Pasteurized Whole Milk.

Conclusions in the final report of the independent US-lab about the trials to receive the AOAC approval for Singlepath E. coli O157:

- The Merck Singlepath EC 0157 *G*old *L*abeled *I*mmuno*S*orbent *A*ssay (GLISA) assay can identify *E. coli* 0157:H7 72-96 hours faster than the BAM reference method.
- There appears to be a good correlation between the results of the Merck Singlepath EC 0157 *G*old *L*abeled *I*mmuno*S*orbent *A*ssay (GLISA) and the BAM reference method.
- The EC Singlepath 0157:H7 test is a very user friendly assay. It requires minimal preparation and set-up, and it is not as labor intensive as the reference method.
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Rapid and simple detection of *E. coli* O157:H7 in water samples after enrichment with ReadyCult®

Andreas Bubert[1], Gabriel Paiva[1], Teresa Smith[2], and Michael Bülte[3]

Poster WQTC Conference , Philadelphia , USA , November 2003

The presence of highly pathogenic *E. coli* O157:H7 in water samples after enrichment in ready-to-use culture media can be easily detected by using an inexpensive indol test. If positive, Singlepath® E. coli O157 can then be applied directly without further preparation of the sample.
No *E. coli* O157:H7 strain used showed any fluorescence in both Readycult® and Colilert-18 samples. In addition, some *E.coli* O157:H-, which can lead to EHEC disease, also failed to provide fluorescence. For Readycult® and Colilert-18 these pathogens can only be classified as coliforms, but identification as *E. coli* is not possible. However, when the indole test was applied to the Readycult® samples, all *E. coli* strains including *E.coli* O157:H7 and :H- showed the typical red ring on the sample surface.
In conclusion, if *E.coli* O157:H7 is present in a water sample, care should be taken as to what method to be used for the analysis. The Readycult® method today is the only USEPA approved method which allows the indole reaction directly in the broth. A positive indole reaction plus a positive reaction on the Singlepath® E. coli O157 lateral flow test (see Fig. 3) confirm the presence of pathogenic *E.coli* O157 isolates in less than 30 minutes after overnight enrichment of the water sample in Readycult®.

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Singlepath® *Campylobacter*: Development and Evaluation of an immunological rapid test for the detection of pathogenic *Campylobacter* spp. from foods

Thompson, Lisa[1]; Lindhardt, Charlotte;[1] Bubert, Andreas[2]; Leusch, Hans-Georg[3]

[3]Inlab GmbH, Dortmund, Germany

Poster DGHM Meeting, Karlsruhe, Germany , March 2002

Singlepath® Campylobacter is highly sensitive and very specific.The test is simple to handle, can be quickly carried out and is easy to evaluate. Singlepath® Campylobacter can be recommended for routine diagnostics.Specificity and sensitivity of the rapid test (in comparison with biochemical culture methods) were measured at 98% and 100%. Singlepath® Campylobacter can therefore be considered to be very safe.
In comparison with VIDAS *Campylobacter,* Singlepath® has the advantages of a much shorter detection time, simpler handling and a more attractive price. For routine testings this results in a clear decrease of operating costs. Occasional false-negative or false-positive results can never be completely excluded with biological material and do not reduce the applicability of the tested methods.

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GLISA FOR DETECTION OF SALMONELLA FROM FOODS OF ANIMAL ORIGIN

Hattendorf P., V. Schönenbrücher und M. Bülte

Poster DGHM Garmisch-Partenkirchen, Sept. 2002

Dept. Vet. Food Science, Justus-Liebig-Universität Gießen, Frankfurter Straße 92, 35392 Gießen, Germany

Singlepath® *Salmonella*- is a very robust, easy to use, and safe test system. Compared to the standard reference method, Singlepath® Salmonella provides earlier and reliable results.

GLISA FOR THE DETECTION OF LISTERIA FROM FOODS OF ANIMAL ORIGIN

SIMON, P., SCHÖNENBRÜCHER, H., AND M. BÜLTE

POSTER DGHM GARMISCH-PARTENKIRCHEN, SEPT. 2002

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Singlepath® Listeria from Merck is as simple, rapid and easy to interprete as the "Listeria rapid test" from Oxoid. Results are obtained within 45 h.

All pure test strains gave reproducible reliable results with both methods (Fa. Merck, Fa. Oxoid), so the sensitivity and specificity determined was 100 %. The „Singlepath® *Listeria*" is a user-friendly rapid screening test for detection of *Listeria* in foods of animal origin, that is suitable for routine diagnosis