

*World
class
pioneers*

Medix Biochemica specializes in monoclonal antibodies and diagnostic tests for numerous medical conditions. Medix Biochemica has succeeded in combining the scientific community and high-tech diagnostics.

More than twenty years ago, we were one of the first companies in the world to produce monoclonal antibodies. We immediately understood their enormous potential in healthcare. Today Medix Biochemica is a dynamic high-tech corporation with a global customer base.

*Reliable
test results
in minutes*



actim™

As a result of our respected global reputation, more than 150 companies in over 30 countries use medixMab™ monoclonal antibodies and numerous laboratories and physicians rely on our actim™ diagnostic healthcare tests.

High quality has always been the cornerstone of all our operations. Our entire company is certified as being in conformity with ISO 9001. In addition, all operations related to diagnostic products have been certified as being in conformity with ISO 13485. We also value research and development. Currently over 20% of our turnover is devoted to R&D.

Our expertise covers the whole production chain from raw materials (monoclonal antibodies) to finished healthcare products, such as the actim™ diagnostic tests.



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*Assessing
CRP levels
in newborns.*



actim™ CRP
SENSITIVE



MAENBR131131-01

Assessing extremely low CRP levels in newborns

Early-onset neonatal sepsis is a serious health threat especially for preterm infants. The rapid actim™ CRP Sensitive dipstick test can detect CRP levels as low as 0.2 mg/l in just 5 minutes.

Most newborns with early-onset neonatal sepsis present symptoms within the first 24 hours. Onset is most rapid in premature neonates. Culture-proven early-onset sepsis develops in about 2% of all infants with birth weight under 1,500 grams. However, ten times more infants are treated as if they are infected.

Early-onset sepsis is commonly associated with micro-organisms, such as *Streptococcus*, *Escherichia coli*, *Haemophilus influenzae* and *Listeria monocytogenes*, contracted from the mother while passing through the colonized birth canal at delivery.

Early detection of neonatal sepsis

CRP (C-Reactive Protein) is an acute-phase protein produced rapidly in response to inflammation, infection and tissue damage. It is used in particular to differentiate bacterial infections from virus infections.

A CRP measurement combined with careful clinical assessment is a valuable tool for initiating immediate antibiotic treatment for neonatal sepsis. This is essential because of the neonate's immunologic weakness in fighting infection.

The normal CRP measuring methods cover the range from 10 mg/l upwards, but in newborns the normal range of CRP in the neonatal cord blood is 0.011 to 6 mg/l. Preterm babies have even lower CRP levels than term babies.

An infection can increase the individual CRP concentration a hundredfold in just one day, but conventional CRP tests cannot distinguish this rise, (see figure). An extremely sensitive CRP test is therefore needed for the accurate diagnosis of infections in newborns.

Actim™ CRP Sensitive test

The actim™ CRP Sensitive test has been developed for detecting early-onset neonatal infections especially in preterm infants. It is an immunochromatographic semi-quantitative rapid test based on monoclonal antibodies, which makes the test highly specific to CRP.

The actim™ CRP Sensitive test helps medical professionals in reaching the right conclusions on the spot, detecting CRP levels as low as 0.2 mg/l.

A minute sample is enough

The actim™ CRP Sensitive rapid test is easy to perform, while minimizing discomfort to the infant. All that is needed to perform the test is a tiny drop – just 10 µl – of whole blood. The sample is obtained with an end-to-end capillary from the heel of the newborn and the capillary is transferred into the specimen dilution buffer.

After dilution, simply dip the actim™ CRP Sensitive dipstick in the diluted sample until the liquid front has risen to the result area. The dipstick is then placed in a horizontal position for five minutes.

Easy to read results in 5 minutes

The results of the actim™ CRP Sensitive test are easy to read. The more CRP the sample contains the more blue lines become visible: a reading with no blue line means a CRP of under 0.2 mg/l, one line means 0.2 to 1 mg/l, two lines 1 to 5 mg/l, and three lines a CRP of over 5 mg/l. A red control line in the result area of the dipstick indicates the test was correctly performed. Accurate results are ready in just five minutes.

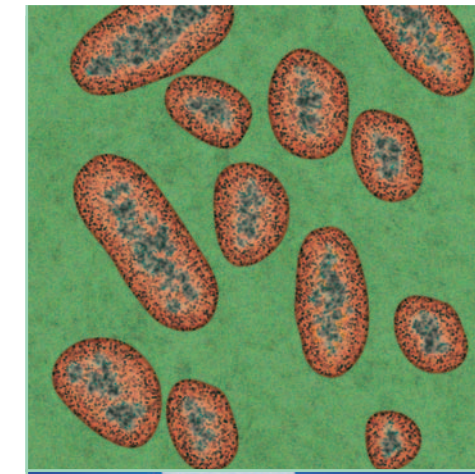


Serum CRP concentration in individual preterm neonates with confirmed bacterial infection. 104 preterm infants without clinical or laboratory evidence of infection (shaded line). 9 cases with confirmed infection (black line).

Literature

Wasunna A, Whitelaw A, Gallimore R et al. C-reactive protein and bacterial infection in preterm infants. *Eur J Pediatr* (1990) 149:424-427.

Ishibashi M, Takemura Y, Ishida H. C-reactive protein kinetics in newborns: application of a high-sensitivity analytic method in its determination. *Clin Chem* (2002) 48:1103-1106.



The actim™ CRP Sensitive test can be performed on the spot. A simple dipstick test is all that is required to assess low CRP levels in newborns.



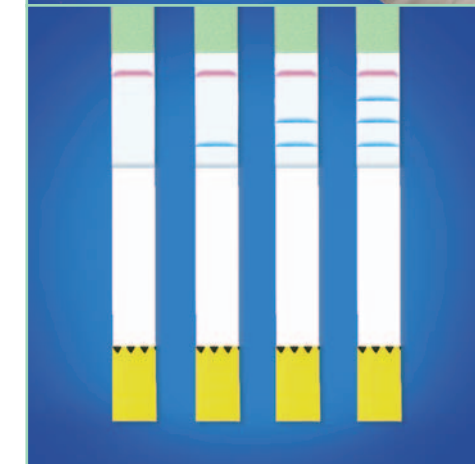
The test kit contains all the necessary materials for sample collection and testing.



Take the sample with an end-to-end capillary from the heel of the newborn.



Dip the actim™ CRP Sensitive dipstick in the sample, place it in a horizontal position and wait for five minutes.



A reading with no blue line means a CRP of under 0.2 mg/l, one line 0.2 to 1 mg/l, two lines 1 to 5 mg/l, and three lines over 5 mg/l.

