



Axis-Shield POC

Happy Audit Steering Committee
Meeting

September 12-13th 2008

Axis-Shield - Point of Care Division

- + 45 years in the IVD business
- + Focus on PoC products
- + 170 employees
- + Consolidated turnover £ 25 million
- + Products sold in more than 80 countries



Resources

- + Area Managers and local distributors covering Spain, Lithuania, Kaliningrad and Argentina
 - Spain: Area Manager Margrete Goksøyr and local partner Novalab Iberica
 - Lithuania: Area Manager Detlef Janke and local partner MedFarnos
 - Kaliningrad: Area Manager Detlef Janke and local partner BioChemMack
 - Argentina: Kim Rørmark and local partner Innova
- + International Product Manager: Eldri Prestegaard
- + Marketing Director: Kjersti Grimsrud



NycoCard® CRP test system

NycoCard® **CRP** Single Test

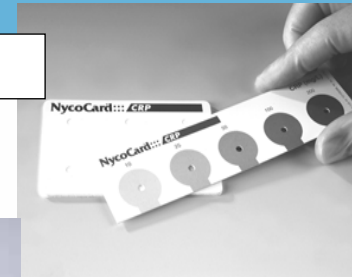


NycoCard[®] CRP - history

One of the first quantitative CRP PoC tests!

- + 1989-4Q: Se/PI test with visual reading
- + 1990-3Q: Whole blood test with visual reading
- + 1992-4Q: Instrumental reading (Reader I)
- + 2000-4Q: NycoCard[®] CRP Single Test
Launch in the Nordic area
- + 2001-2Q: Launch in Switzerland and Germany
- + 2002-2Q: FDA 510(k) approval
- + 2002-3Q: Launch in USA and Japan
- + 2008: World wide sales

1989: Visual reading



1992: Reader I



2000:
NycoCard[®] CRP Single
Test and Reader II



NycoCard[®] CRP test system

- + Test time less than 3 minutes
- + One kit and one test procedure for all sample material
 - capillary or venous blood, serum or plasma
- + 5 µL sample volume
- + Broad measuring range
 - CRP 8-200 mg/L (whole blood samples)
 - CRP 5-120 mg/L (serum/plasma samples)
- + Reliable results
 - Correlates well with laboratory methods
- + Low investments and test price
- + NycoCard[®] Reader II – a multiassay analyser



NycoCard® READER II



- + Precise and accurate reading of test results
- + Easy handling
- + One instrument for all NycoCard® tests
 - NycoCard® CRP
 - NycoCard® HbA1c
 - NycoCard® U-Albumin
 - NycoCard® D-Dimer

Kit contents: 48(24) Tests



- + TD/Test Device 2(1) x 24 units
- + R1/Dilution Liquid 2(1) x 26 tubes
- + R2/Conjugate 3.5 mL
- + R3/Washing Solution 3.0 mL
- + C+/Control Positive 0.5 mL
- + Capillary tubes 60 units
- + Package insert

Equipment not supplied with the kit



- + Mini-Pet 50 µL
- + Pipette tips

- + Capillary tube holder
- + Lancets

NycoCard[®] CRP test procedure



1) Add 5 μ L sample or Control to the Dilution Liquid



2) Add 50 μ L diluted sample to the Test Device



3) Add one drop Conjugate



4) Add one drop Washing Solution



5) White calibrate the Reader



6) Read the result

What can we provide?

- + Committed and highly skilled personnel
- + Project Management in Oslo
- + Support at Local Meetings and conferences
- + Training of participants (GP and nurses) including familiarisation and follow up
- + "Start Package"
 - Everything the GP/nurse need to perform the tests
- + Troubleshooting and support locally (local partners)
- + Organizing and logistics



What can we provide?

+ "Start Package" for the GP/nurse

- One box containing everything the GP/nurse need to perform test
 - NycoCard Reader II
 - NycoCard CRP kits and Controls (cool storage)
 - Accessories; racks, pipettes and pipette tips
 - Training material in local language
 - Troubleshooting guide in local language
 - Contact information with local support- **HOT LINE**
- To be shipped to the Health Centre
- Strep- A for Lithuania and Kaliningrad will be included in the "Start package"



What can we provide?

- + Training of participants (GP and nurses)
 - Training at local meetings
 - Axis-Shield and local partner will conduct training
 - Each site will receive start package after training
 - Each operator should after training, close to inclusion, perform familiarisation
 - If familiarisation OK, Start up
 - If not OK, follow up and further training will be given
 - Visit by local partner if required

- + Technical support/ Troubleshooting during inclusion phase
 - Local phone number for support in local language will be available
 - Back up

- + Organizing and logistics



Status in Lithuania- NycoCard[®] CRP and Strep-A

- + Axis-Shield PoC (E. Prestegård) will attend the first follow up meeting 19-20th September in Palanga
 - Presentation by E. Prestegård: „Diagnostic methods in respiratory tract infections in primary care“
 - Focus on the CRP and Strep A tests with training material.
 - Plans for training and setup of test equipments for GPs and/or nurses/assistants.

- + Training and setup of the test equipments
 - Axis-Shield PoC (Eldri Prestegård and Detlef Janke) will be responsible
 - MedFarmos will take care of the local training and setup of test equipment
 - Material in preparation for the training and inclusion period (in local language)
 - All material will be shipped in week 40 to MedFarmos
 - MedFarmos will visit the study sites one by one for training and setup



Status in Kaliningrad- NycoCard[®] CRP and Strep-A

- + Axis-Shield PoC (D. Janke) will attend follow up meeting 20th September in Kaliningrad
 - Presentation by D. Janke: „Course material for professionals, microbiological test equipment for GPs and intervention material for professionals“

- + Training session on the 11th of October at the follow up meeting in Svetlogorsk
 - Material for the training in preparation
 - Material will be shipped in week 40
 - Eldri Prestegård and Detlef Janke from Axis-Shield PoC organize the training session
 - BioChemMack will support Axis-Shield at this meeting with two persons (Yevgeniy Yegorov, Sergey Romanov)

- + 2nd registration 2009
 - BiochemMack will be the contact for technical support



Input request from Spain

- List of participants in each region
 - Health Centre, GP`s Name, Nurses` name and address
 - Name and contact information of Happy Audit coordinators
 - Responsible person in HC
- Meeting dates and participant list
 - Training of GP and /or nurse?
 - Meeting structure and time available
- Training
 - Training at Second Meeting
 - Organizing at HC
- Shipping
 - Local partner will ship the start kit to the site after training
 - Receive familiarisation results and check that results are OK
 - Support with kits



Greetings from Oslo!



Axis-Shield PoC

