

# focus on Laboratory Products

## Is this the Extinction of ESR, the Dinosaur Laboratory test?

Sabrina Chetcuti, Marketing Manager, Benson Viscometers Ltd

Many laboratories have historically clung onto the ESR (Erythrocyte Sedimentation Rate) as a test that can confirm that patients are unwell.

Even though the science behind ESR is seen as dubious by laboratory scientists and many clinicians including Consultant Haematologists, the question that remains unanswered is why we are still requesting it?

Is it just out of habit that we continue to use a test that has no quality control and results will vary without any change in the patient condition? Aspirin and Steroids are the backbone of many treatments for patients with inflammation, and yet they are the very drugs that will significantly interfere with the ESR results, suggestive of an improvement that may not have occurred.

Plasma Viscosity (PV) testing was seen as the 'cure' for this habit more than 30 years ago, and yet this 'easy to use', rapid, stable diagnostic tool has been overlooked by many laboratories as the high volume alternative. Over the years more and more laboratories have elected to use Plasma Viscosity testing as a significant tool within their repertoire. Some noteworthy centres of excellence have taken the ambitious commitment to eliminate ESR in preference for PV including Leeds General Infirmary, Royal United Hospital Bath, Nobles Hospital IOM and Royal Devon and Exeter.

Recently the momentum for change appears to have taken some significant steps forward in the laboratory drive for increased efficiency and modernisation, as more sites across the UK signal a sea change in breaking age old habits around ESR.

NHS Highland and Hull Royal Infirmary (HEY NHS Trust) are the latest Trusts to have abandoned their ESR testing in preference for PV by working with their clinical community to drive that change. The laboratories took advantage of a reorganisation in Haematology, to overhaul the service and move to a more efficient system.

"You need to be able to get consistent results in order to provide useful data for the clinical community. With PV we have internal and external QC (CQAS). Due to the excellent data CQAS provide and the total number of Benson analysers the consistency is easily observable. The manual ESR system did not have its own QC and no external quality control was available," said Mick Milner, NHS Highland.

These new sites have been able to provide some insight into how they achieved the change with the full support of their clinical colleagues. Together with the longer term experiences of the Royal Devon and Exeter Hospital (RD&E), a process route map has been developed, and could be followed by those laboratories that would also like to eliminate ESR testing, potentially reduce costs and provide the means to monitor post acute phase inflammatory disease progression.

### Process route map to introduce routine Plasma Viscosity testing Successful Change Steps

#### 1. Assessment

- Review of clinical picture and patient data repeatedly shows that PV provides a more consistent indicator of disease progression and demonstrates the clinical significance of very small (0.05mPa.s) changes.
- Duplicate test data for ESR and PV shows there is no conversion table between the two systems.

#### 2. Consultation with specialist clinicians and GP's to highlight changes

- The simplification of the test profile by the potential elimination of additional blood collection tubes (PV can use the full blood count sample).
- Improvements due to plasma sample stability and viscosity testing quality control.
- Rheumatology/Speciality patient monitoring change to CRP for acute phase.
- Handling of clinical trial requirements.

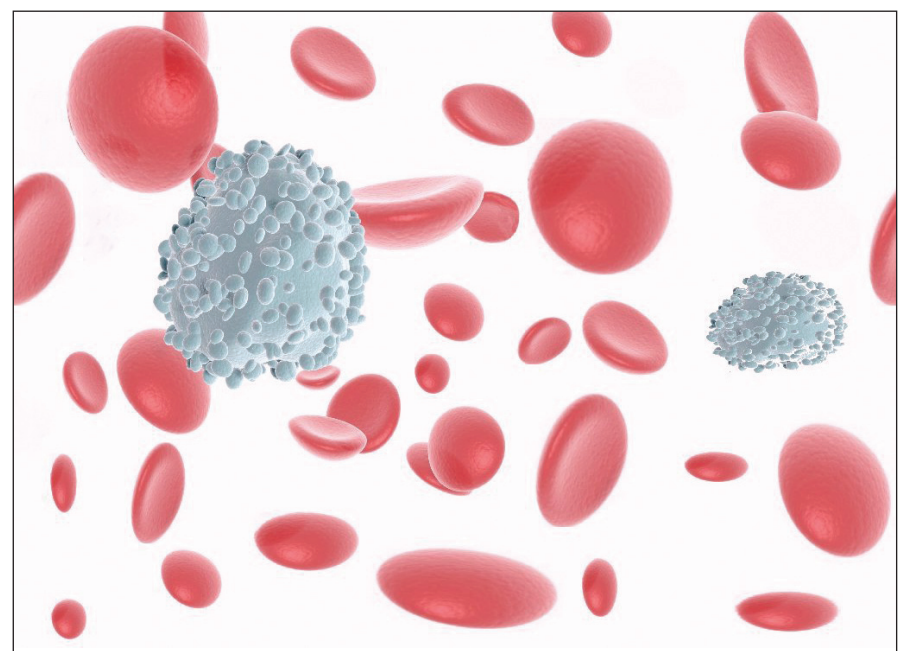
#### 3. Issue notice period for the switch to PV

- Include summary evidence for the change.
- Include table for results interpretation.
- Plan for a short switch over period.

#### 4. Support Clinicians and specialities to make the final move

- Provide laboratory staff with training to answer questions from clinicians.

#### 5. Seek feedback



A focus on four key areas was identified during the consultation to support the transition period: Rheumatology, Orthopaedics, Clinical Trials and GP's.

NHS Highland found that some basic clinical trial packages used ESR testing results due to clinical convention. Discussions revealed that the ESR results themselves did not alter patient management neither did the majority of trials really require its use.

The Royal Devon and Exeter (RD&E) hospital managed to eliminate all ESR testing four years ago. Steve Walton, Haematology Laboratory Manager at the RD&E explained that the only area of difficulty was for one WW clinical trial. A drug used as part of a hip replacement procedure was only available following an ESR test result. This drug authorisation protocol is not routinely seen in arthritic hip replacement surgery. The Orthopaedic surgeons and the Microbiologists routine plan of action is the continued use of CRP to check for the acute phase inflammatory response in a two stage operation where the patient's new hip is only inserted if there is no sign of infection. Once the critical phase is completed then PV testing is routinely used to monitor.

Similarly, NHS Highland Rheumatologists use routine CRP test for tracking patient progress with disease assessment scores and were able to eliminate ESR.

The consultation and support processes were handled as critical steps in reviewing the potential for changing away from ESR testing. NHS Highland Consultant Haematologist Dr Peter Forsyth drove the decision to make the change only after preparing the evidence base, where it was found that PV provided the laboratory with consistent, stable and reproducible data. This enables the requesting clinicians to plot disease progression with cumulative PV data. The information was provided as part of a consultation of the GPs and Hospital Consultants and with the question – what would happen if we withdrew ESR? The decision overall was that PV would provide a suitable alternative.

"Having put a good evidence base together we found that PV gave us consistent data, it was easier, a separate specimen tube was not required and with increased numbers would provide some additional financial savings," said Dr Peter Forsyth.



Mick Milner goes on to explain that education is critical. The clinicians require clear information of what a PV result means because the range appears limited. Compared with wide ESR scale of <8mm to 120mm, the PV normal range is only 1.50 to 1.72 mPa.s. The laboratory has been posting additional information on their reports to assist the clinician's interpretation

Time and sample transportation can give significant challenges for any integrated system involving several laboratories and GP point of care services. Both NHS Highland and HEY NHS Trusts found that switching to PV testing helped them overcome difficulties in managing the return of samples from outlying clinics.

"The test became pointless when specimens arrived from outlying areas already 24 hours old. We made the decision to stop providing the ESR within our test repertoire. PV's on the other hand provided a stable repeatable result, a major consideration given our unique geography," said Mick Milner, NHS Highland.

## Satisfying Feedback

As one of the most important vehicles for communication and process improvements, the prospect of adverse feedback often causes some trepidation. Across all three Trusts, the feedback received was very positive.

"There were a lot of glowing comments from the feedback questionnaires. The only complaint we received was that the turn around time was now too quick – glowing praise indeed," said Elaine Boyle, Haematology Service Manager Hull Royal Infirmary, HEY NHS Trust.

## Testing Profile Comparisons

Since the early investigations J Harkness (Biorheology 8: 171-193, 1971) there have been a number of research publications that have compared ESR measurements with Plasma Viscosity. This can be best summarised by the following comparison of the potential for each technology to provide patient screening information.

## Case for Change

Both Plasma Viscosity and ESR have been used to 'screen' for the presence of infection or inflammation and to monitor 'disease activity' but the significant differences between each test have led many haematology laboratories to make the case for change both from a clinical and technical aspect. Over the last few years, there is significant evidence that more laboratories are increasing the momentum to make that change.

With special thanks to;

Elaine Boyle, Haematology Service Manager HEY NHS Trust

Dr Peter Forsyth, Consultant Haematologist, NHS Highland

Mick Milner, Haematology Manager, NHS Highland

Steve Walton, Laboratory Manager RD&E

Patient Condition	Screen/Treatment	ESR	Plasma Viscosity
Chronic Arthritis	Prediction in patients with early rheumatic disorders	No	Yes if combined with Serum Viscosity
Poikilocytosis Rheumatology Chronic Malignancy	Associated with Anaemia	ESR rate increase is difficult to interpret User of ESR to monitor therapy becomes subjective	PV correlates well with disease progression <sup>1</sup>
Polycythaemia	>50%	Normal ESR results found irrespective of underlying disease	PV measurements unaffected
Myeloma Macroglobulinaemia	High Plasma Viscosity	ESR cannot distinguish between conditions. High plasma protein concentration may lead to spurious results	Results are characteristic and very high results are suggestive of either condition.
Anti-inflammatory Treatments	Steroids	ESR readings give normal results even with elevated plasma viscosity Levels <sup>2</sup>	PV results improve only with the arrest of the inflammatory process
	Salicylate Therapy	Drug effect lowers ESR reading	PV results NOT affected directly by the drug
	Glucocorticoids	No	PV monitoring prediction of flare ups <sup>3</sup>
Plasma Hyperviscosity	Diagnosis without false negatives	No	Yes
Variation of reference ranges with age, sex, smoking and pregnancy		Different normal ranges for men and women  More variation for other factors	Age (after 3 years) gender and diurnal rhythms have no effect on PV. Only consistent physiological factor during pregnancy is a rise of PV in the final trimester
Patient Management	Intersystem effect	System Variations and methods will NOT allow comparisons	One standard for universally comparable results

[1] Ng T. Erythrocyte sedimentation rate, plasma viscosity and C-reactive protein in clinical practice. Br J Hosp Med 1997;58:521-3  
 [2] Brittain GPH, McIlwaine GG, Bell JA, Gibson JM, Plasma viscosity or erythrocyte sedimentation rate in the diagnosis of giant cell arteritis. Br J Ophthalmol 1991;75:656-9  
 [3] Gudmundsson M, Nordborg E, Bengtsson B-A, Bjelle A. Plasma Viscosity in giant cell Arteritis as a predictor of disease activity. Ann Rheum Dis 1993; 532: 104-9



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