

Assessment Schemes in Immunology,  
Allergy and Immunochemistry:

Report Interpretation/Scoring

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Portugal

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## Programmes for Autoimmunity

- General Autoimmune Serology
  - Rheumatoid factor
  - Antibody to thyroid peroxidase (TPO)
  - Mitochondrial antibody
  - Liver-kidney microsome (LKM-1) antibody
  - Smooth muscle antibody
  - Gastric parietal cell antibody

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## Programmes for Autoimmunity

- Antibodies to Nuclear and Related Antigens
  - Antinuclear Antibody (ANA)
  - dsDNA Antibody
  - Extractable nuclear antigens (ENA)
  - Indirect immunofluorescent staining patterns (HEp2 cell)

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## Programmes for Autoimmunity

- Phospholipid Antibodies
- Neutrophil Cytoplasmic and GBM Antibodies
- Acetylcholine Receptor Antibodies

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## Quality Assurance in Autoimmunity

- Materials used for distribution:
  - Normal human serum
  - Pathological single donor human serum
  - Distributed in liquid form
  - Validated prior to dispatch

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## Quality Assurance in Autoimmune Serology

- Reports show kit or method related statistics.
- Individual laboratory performance based on 2 systems:
  - Misclassification Index Score (MIS) system- qualitative results
  - Variance Index Scoring (VIS) System- quantitative result

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## Misclassification Index Scoring System

- This is an indication of the number of times that a laboratory has returned a result which is not the same as the Designated Response(DR).
- Misclassification Index Score (MIS) – the number of times that a particular laboratory has give a wrong results in a defined period of time for a given analyte.

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# Misclassification Index Scoring System

- Overall Misclassification Index Score (OMIS) – the cumulated MISs for **all** of the analytes in a scheme during a defined period of time.
- The **ideal** score is zero!

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UK NEQAS for General Autoimmune Serology

Distribution : 065      September 2006      Participant : 656

643 out of 774 participants returned data for this distribution. 83% response rate.

**Nil Responses**

5A, R4, 100, 120, 121, 157, 177A, Z179, 206C, 262, 282, 351, 560, 674R, 691, 1128A, 1522, 1568, 1583, 1657, 1674A, 1690, 1774, 2081, 2085, 2088J, 2088JR, 2184X, 2206, 2209A, 2218JR, 2222, 2242JR, 2244JR, 2245JR, 2247JR, 2248JR, 2273, 3608, 3911, 3916, 3923, 3924, 3956X, 3966, 3972X, 3982X, 3993X, 4018, 4033, 4040A, 4072, 4079, 4137, 4169, 4197, 4206R, 4241, 4284, 4317A, 4318A, 4371, 4416, 4438, 4440, 4486, 4494, 4514, 4558, 4800, 4605R, 4615A, 4620, 4637, 4654, 4655, 4662, 4680, 4682, 4806, 4810, 4811, 4830, 4851, 4855, 4857, 4873B, 4874, 4880, 4884JR, 4896, 5003R, 5011R, 5036R, 5050R, 5070R, 5084, 5123R, 5050R2, 90114, 90177, 90190, 90230, 90413, 90404X, 90602J, 90717, 90739, 91054X, 91063X, 91139J, 91186, 91238, 91242, 91276, 91353X, 91413, 91494, 91528, DRG, BIOS, CODEX, INFO, SEQC, TVN, VAR

**Sample 0651** was a single donor serum from a patient with rheumatoid arthritis.

**Sample 0652** was a single donor serum from a patient with active thyroid disease.

**Sample 0653** was a single donor serum from a patient with autoimmune hepatitis.

**Sample 0654** was a pooled NBS donor serum.

Sample	Analyte	Positive	Negative	Target Response	Your Response	Score	Analyte MIS
0651	Rheumatoid Factor	351	6	Positive	Positive	0	3
0652	Thyroid Microsome Antibody/TPO	329	4	Positive	Positive	0	0
0653	Mitochondrial Antibody	217	155	Equivocal	Negative	0	0
0653	LKM-1 Antibody	16	319	Negative	Negative	0	0
0653	Smooth Muscle Antibody	1	348	Negative	Negative	0	1
0654	Gastric Parietal Cell Antibody	3	291	Negative	Negative	0	0
<b>Total MIS</b>							<b>4</b>

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## Programmes for Immunochemistry

- C.Reactive Protein (CRP)
- Ultrasensitive C.Reactive Protein (UCRP)
- Beta 2 Microglobulin
- CSF Proteins and Biochemistry
- CSF IgG Oligoclonal Bands
- Bone Metabolism Assays

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## Programmes for Oncology

- Prostate Specific Antigen
  - Total PSA, Free PSA, complexed PSA
- Tumour Markers
  - CA125, CA153, CA199, NSE
- Monoclonal Protein Identification

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## Programmes for Allergy and Immunodeficiency

- IgG Subclasses
- Specific Microbial Antibodies
- Antibody to Fungal and Avian Antigens
- Total IgE
- C1 Esterase inhibitor and functional complement assays

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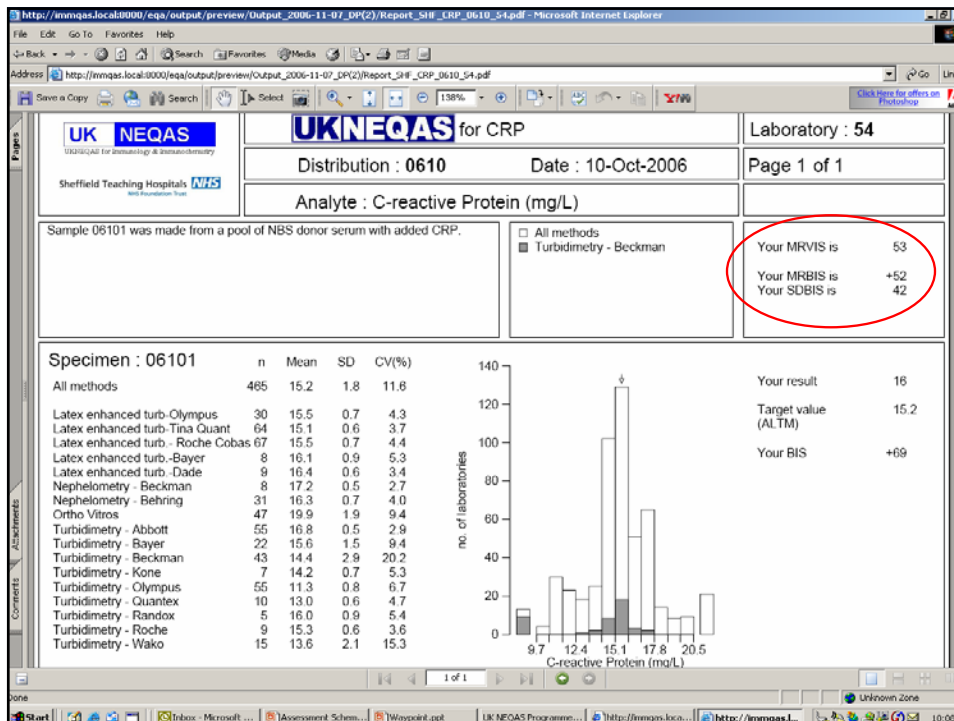
## Programmes in Allergy and Immunodeficiency

- Allergen Specific IgE
  - Dermatophagoides pteronyssinus
  - Animal danders
  - Foods (includes peanut)
  - Grass/tree pollens
  - Venoms
  - Moulds

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# VARIANCE INDEX SCORING SYSTEM

- **Designated Value (DV):** For most schemes and analytes this is the All Laboratory Trimmed Mean (ALTM), but may, in certain situation, be a Grouped Method Mean (GLTM), or a preset value determined by prior definition or distribution.





## VARIANCE INDEX SCORING SYSTEM

- **Chosen Coefficient of Variation (CCV):** An arbitrary scaling factor selected for each analyte to correct for the current state of the art – selected to provide consistent targets of performance.

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## VARIANCE INDEX SCORING SYSTEM

- **Variance Index (VI):** The difference, irrespective of sign, between the results returned and the designated value, expressed as a percentage of the designated value. This is divided by the CCV for the analyte expressed as a percentage.

$$VI = \frac{(\text{result} - DV)}{DV} \frac{10000}{CCV}$$

- **Variance Index Score (VIS):** For values of VI less than 400, VIS=VI. The maximum VIS is 400.
- **Bias Index Score (BIS):** Identical to the VIS but retaining the sign.

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## VARIANCE INDEX SCORING SYSTEM

- **Standard Deviation of the BIS (SDBIS):** gives an indication of the precision of an assay over a defined period of time.
- **Mean Running BIS (MRBIS):** gives an indication of the bias of an assay over a period of time.
- **Mean Running VIS (MRVIS):** contains elements of both bias and precision. Used for the overall classification of laboratory performance.

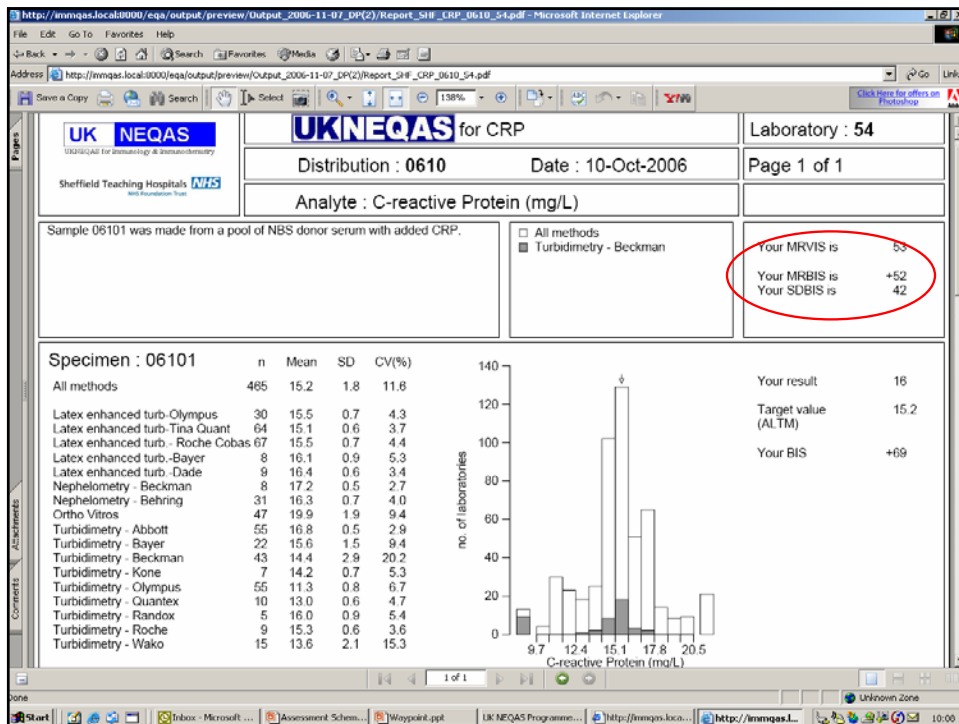
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## VARIANCE INDEX SCORING SYSTEM

- **Criteria of Performance**

Ideal	MRVIS	<50
Good	MRVIS	50 – 100
Adequate	MRVIS	101-200
Poor	MRVIS	>200 <u>or</u> SDBIS >200

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# VARIANCE INDEX SCORING SYSTEM

- Bullock D.G. and Wilde C.E., *Annals of Clinical Biochemistry*, 1985, 22, 273-282.

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