

Dena Laboratory

MATERNAL SCREENING

CYCLE 9 SAMPLE 9

Explanation of codes used in this report

R - Results removed due to reconstitution error
N - No result returned
C - Result corrected

Authorised by: Stephen Doherty, RIQAS Manager

Issue No: 1

Issue Date: 19/09/2017

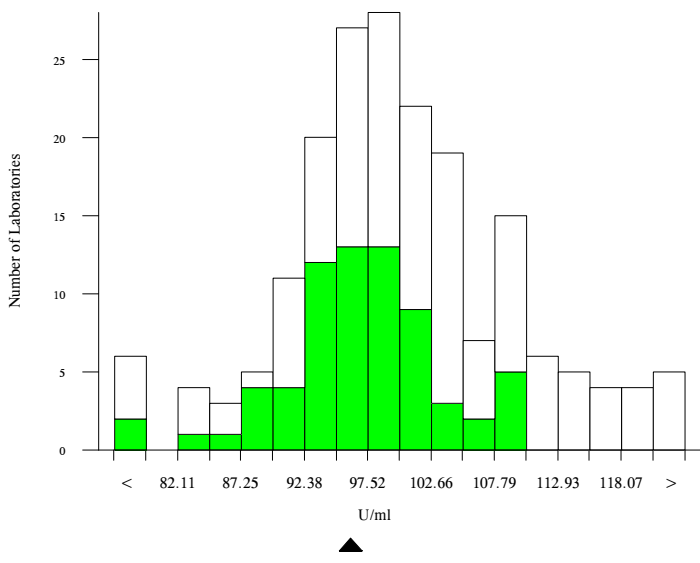
Randox Laboratories Limited
55 Diamond Road
CRUMLIN BT29 4QY
Tel: +44 (0)28 9445 4399
Fax: +44 (0)28 9445 4398
Email: mail@riqas.com

AFP, U/ml

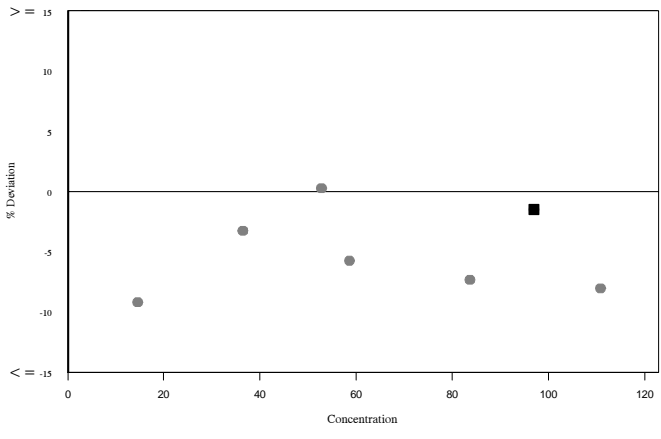
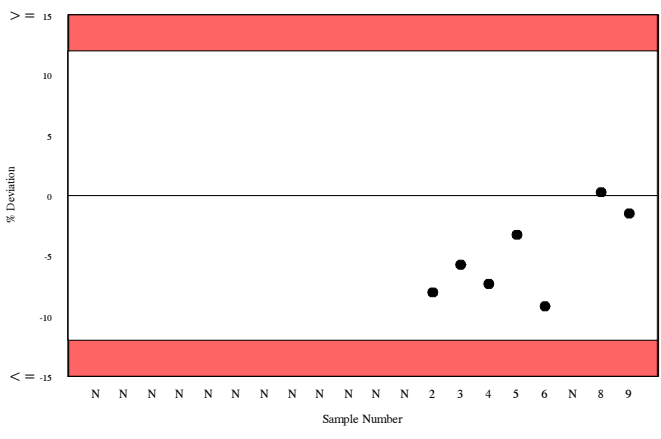
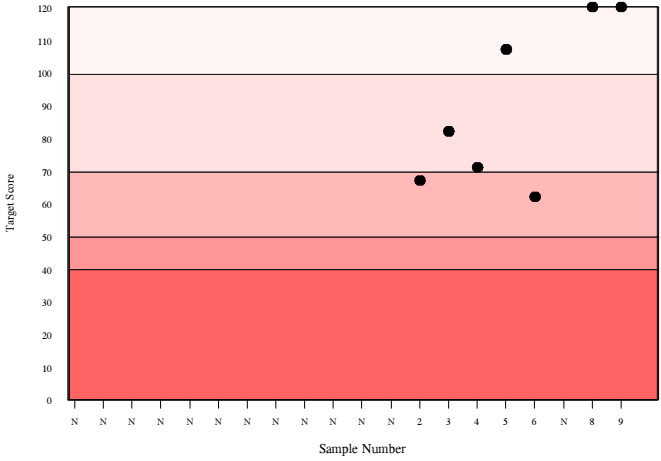
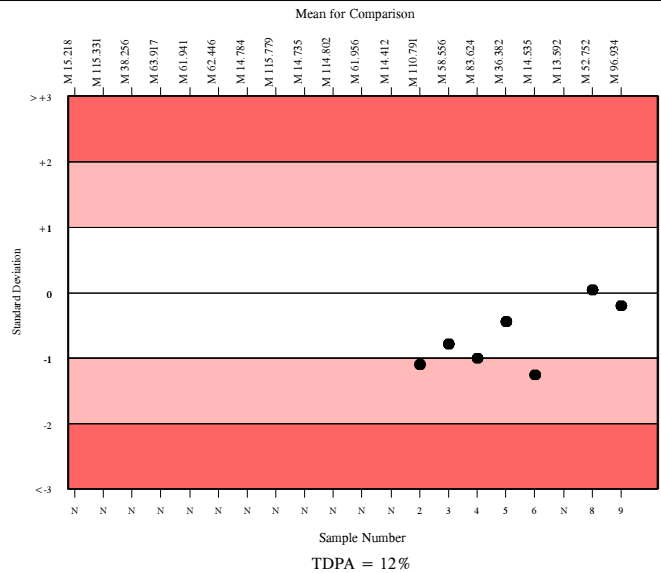
| | N | Mean | CV% | U _m | SDPA | Exc. |
|--------------------------------|-----|---------|-----|----------------|------|------|
| All Methods | 172 | 100.094 | 6.8 | 0.65 | 7.30 | 19 |
| Siemens/DPC Immulite 2000/2500 | 62 | 96.934 | 4.7 | 0.72 | 7.07 | 7 |

| | | | |
|-----------------------|--------|--------|---------|
| ▲ Your Result | 95.500 | SDI | -0.20 |
| | | RMSDI | Too Few |
| ■ Mean for Comparison | 96.934 | TS | 120 |
| | | RMTS | Too Few |
| | | %DEV | -1.5 |
| | | RM%DEV | Too Few |

| | |
|-----------------------------------------------------|--------|
| Acceptable limits derived from Biological Variation | 21.9% |
| Acceptable limits of performance for RIQAS | 12.00% |



| Method | N | Mean | CV% | U _m |
|---------------------------------------|----|---------|------|----------------|
| Siemens/DPC Immulite 2000/2500 | 62 | 96.934 | 4.7 | 0.72 |
| Perkin Elmer DELFIA Xpress/AutoDELFIA | 25 | 100.382 | 2.9 | 0.74 |
| Beckman DxI 600 / 800 | 21 | 95.161 | 5.8 | 1.52 |
| Roche Cobas 6000/8000 | 12 | 110.647 | 4.7 | 1.87 |
| Beckman Access/LXi725 | 10 | 111.191 | 9.0 | 3.96 |
| Abbott Architect | 9 | 98.374 | 2.7 | 1.09 |
| Siemens/DPC Immulite 1000 | 9 | 99.632 | 6.3 | 2.61 |
| Roche Cobas 4000/e411 | 8 | 109.470 | 6.6 | 3.19 |
| Siemens Centaur XP/XPT/Classic | 7 | 113.725 | 4.5 | 2.42 |
| Brahms Kryptor | 4 | 74.219 | 25.7 | 11.91 |

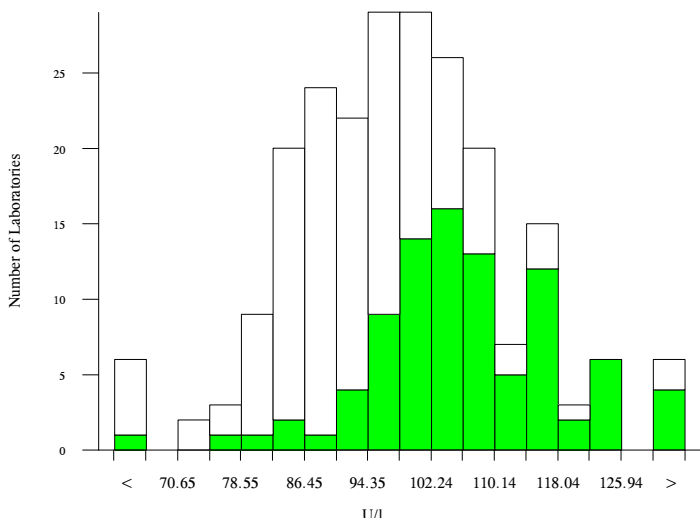


hCG, free beta, U/I

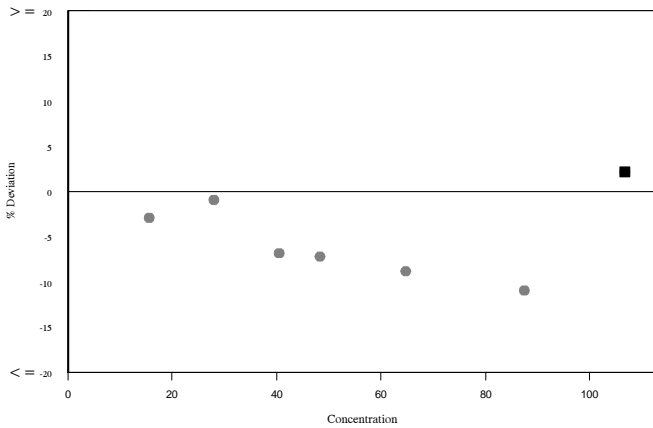
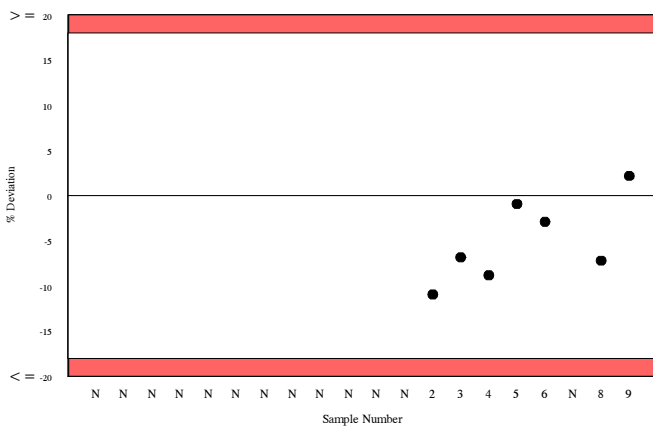
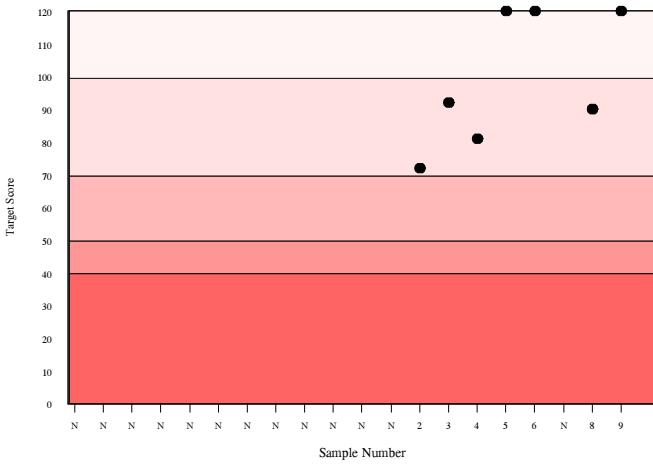
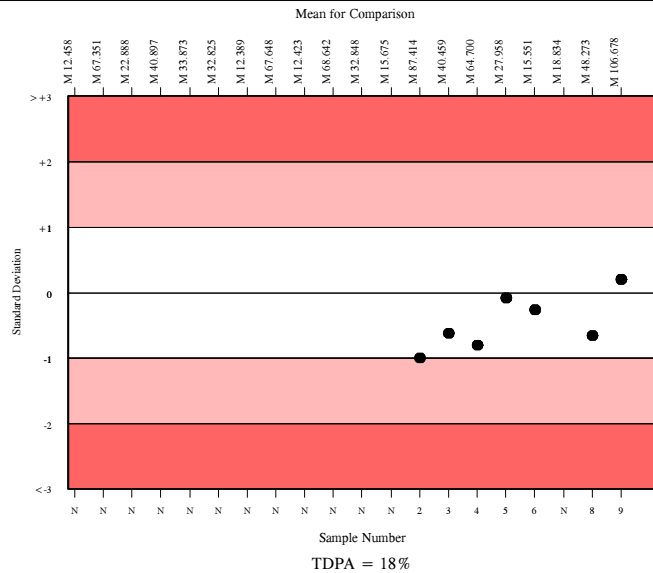
| | N | Mean | CV% | U _m | SDPA | Exc. |
|----------------------------------|-----|---------|------|----------------|-------|------|
| □ All Methods | 210 | 98.300 | 10.7 | 0.91 | 10.76 | 17 |
| ■ Siemens/DPC Immulite 2000/2500 | 82 | 106.678 | 8.0 | 1.18 | 11.67 | 9 |

| | | | |
|-----------------------|---------|----------------|-----------------|
| ▲ Your Result | 109.000 | SDI RMSDI | 0.20 Too Few |
| ■ Mean for Comparison | 106.678 | TS RMTS | 120 Too Few |
| | | %DEV RM%DEV | 2.2 Too Few |

| | |
|-----------------------------------------------------|--------|
| Acceptable limits derived from Biological Variation | N/A |
| Acceptable limits of performance for RIQAS | 18.00% |



| Method | N | Mean | CV% | U _m |
|---------------------------------------|----|---------|-----|----------------|
| Siemens/DPC Immulite 2000/2500 | 82 | 106.678 | 8.0 | 1.18 |
| Perkin Elmer DELFIA Xpress/AutoDELFIA | 37 | 94.754 | 4.0 | 0.77 |
| Roche Cobas 4000/e411 | 25 | 86.971 | 4.3 | 0.94 |
| Roche Cobas 6000/8000 | 24 | 85.791 | 3.9 | 0.85 |
| Brahms, Krytor | 14 | 102.017 | 3.8 | 1.30 |
| Siemens/DPC Immulite 1000 | 10 | 104.776 | 2.8 | 1.15 |



RIQAS



hCG, total, U/ml

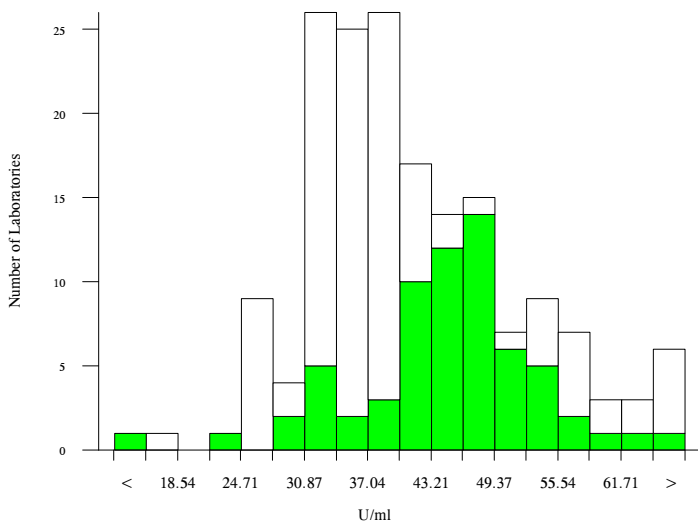
□ All Methods

■ Siemens/DPC Immulite 2000/2500

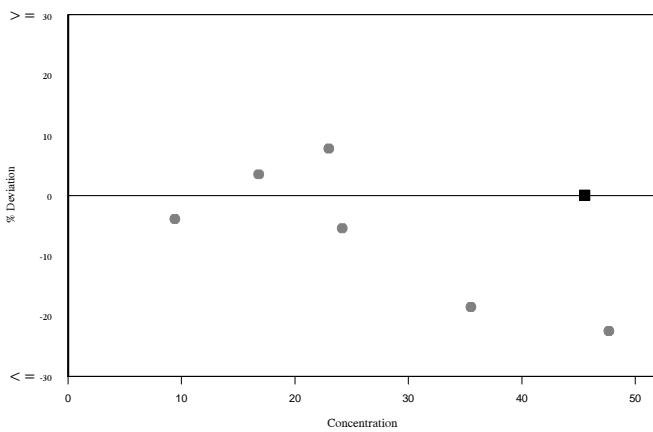
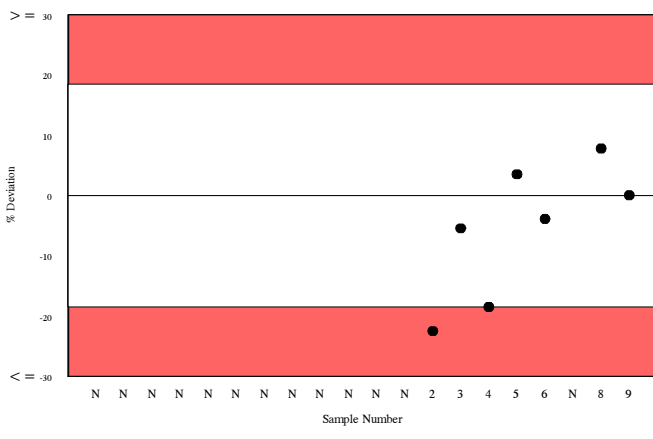
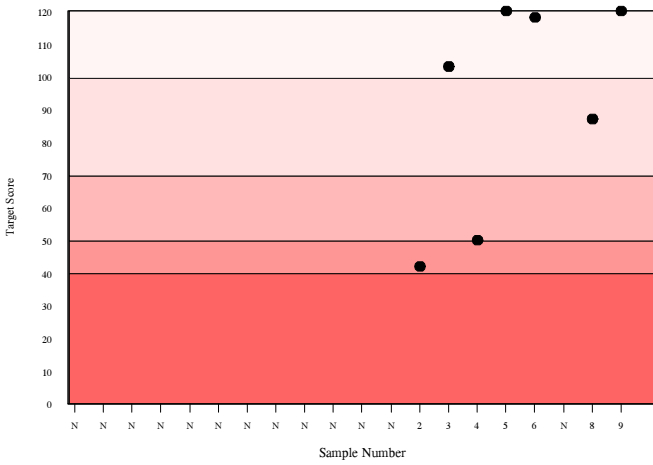
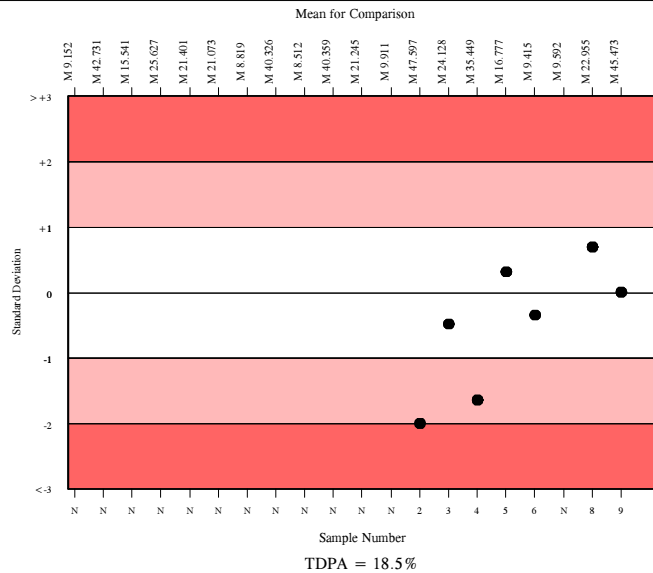
| N | Mean | CV% | U _m | SDPA | Exc. |
|-----|--------|------|----------------|------|------|
| 161 | 40.129 | 20.5 | 0.81 | 4.51 | 13 |
| 60 | 45.473 | 13.9 | 1.02 | 5.11 | 6 |

| | | | |
|-----------------------|--------|--------|---------|
| ▲ Your Result | 45.500 | SDI | 0.01 |
| | | RMSDI | Too Few |
| ■ Mean for Comparison | 45.473 | TS | 120 |
| | | RMTS | Too Few |
| | | %DEV | 0.1 |
| | | RM%DEV | Too Few |

| | |
|-----------------------------------------------------|--------|
| Acceptable limits derived from Biological Variation | N/A |
| Acceptable limits of performance for RIQAS | 18.50% |



| Method | N | Mean | CV% | U _m |
|---------------------------------------|----|--------|------|----------------|
| Siemens/DPC Immulite 2000/2500 | 60 | 45.473 | 13.9 | 1.02 |
| Roche hCG + Beta | 26 | 36.516 | 6.0 | 0.54 |
| Beckman DXI Total BhCG (5th IS) | 16 | 35.516 | 7.8 | 0.87 |
| Siemens/DPC Immulite 1000 | 12 | 55.952 | 18.1 | 3.65 |
| Abbott Architect I2000/8200 | 9 | 32.779 | 3.4 | 0.46 |
| Beckman DxI 600 / 800 | 7 | 35.344 | 11.2 | 1.87 |
| Beckman Access Total BhCG (5th IS) | 7 | 37.829 | 5.5 | 0.99 |
| Siemens Centaur XP/XPT/Classic | 6 | 26.856 | 2.2 | 0.30 |
| Perkin Elmer DELFIA Xpress/AutoDELFIA | 6 | 54.981 | 3.8 | 1.06 |
| Beckman Access | 6 | 37.300 | 6.2 | 1.18 |
| bioMerieux, Vidas/Mini Vidas | 3 | 68.868 | 7.4 | 3.68 |



Inhibin A, pg/ml

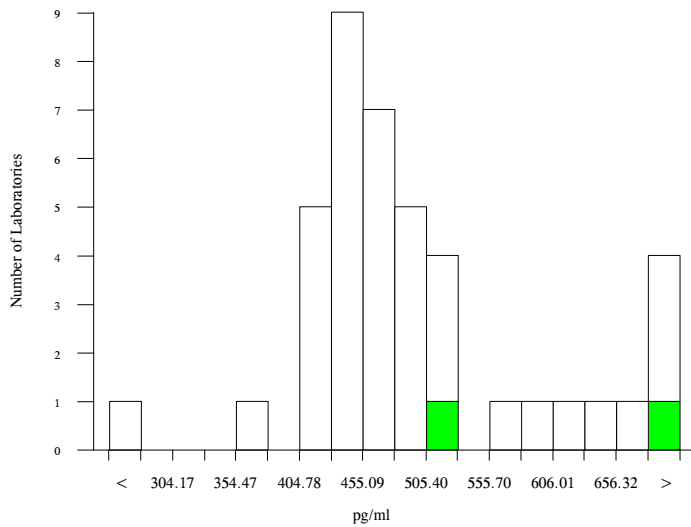
- All Methods
- Stat Fax Elisa Readers

| N | Mean | CV% | U _m | SDPA | Exc. |
|----|---------|------|----------------|---------|------|
| 36 | 480.247 | 14.0 | 13.97 | 47.64a | 5 |
| 2 | 608.050 | 23.5 | 126.31 | 138.85a | 0 |

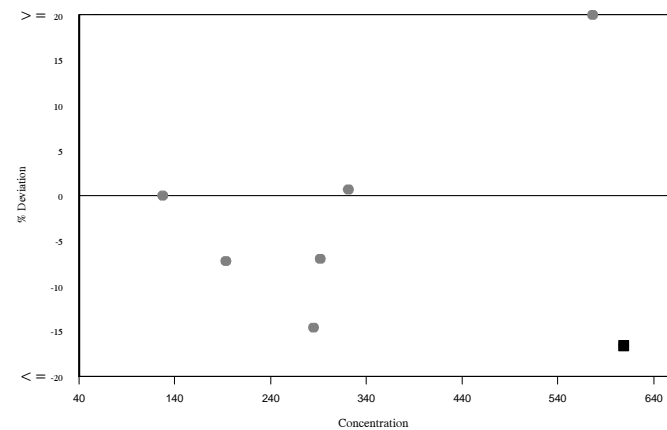
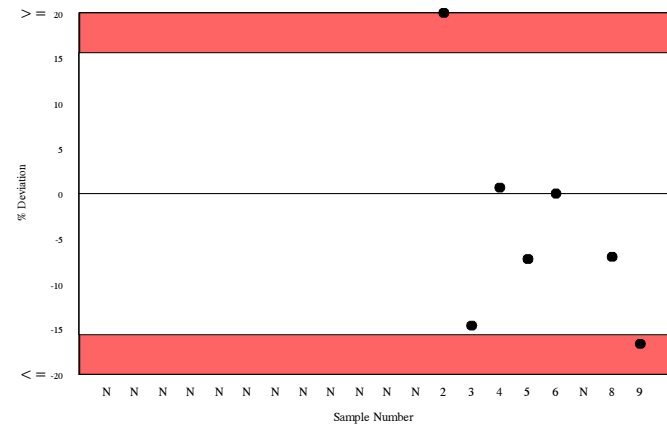
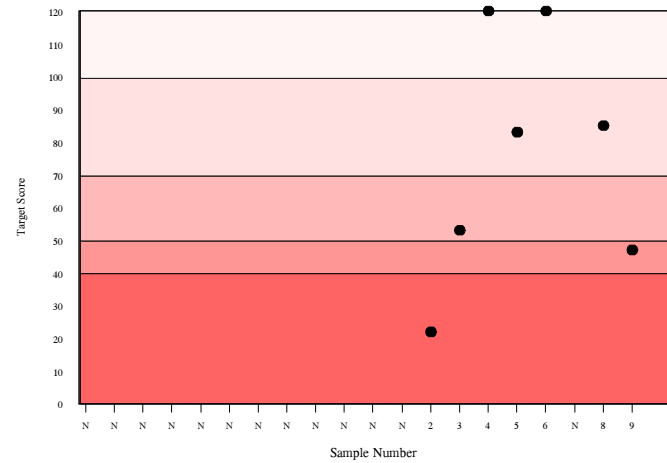
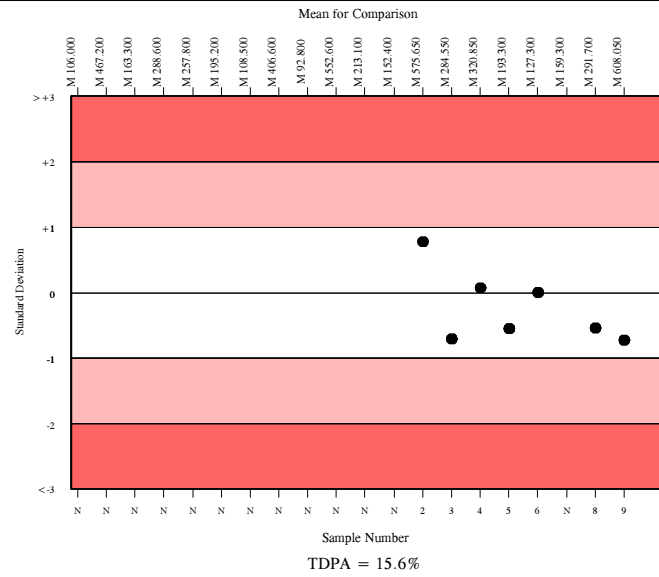
| | | | |
|------------------------------|---------|--------|---------|
| ▲ Your Result | 507.000 | SDI | -0.73 |
| | | RMSDI | Too Few |
| ■ Mean for Comparison | 608.050 | TS | 47 |
| | | RMTS | Too Few |
| | | %DEV | -16.6 |
| | | RM%DEV | Too Few |

The mean for comparison is not statistically significant

| | |
|-----------------------------------------------------|--------|
| Acceptable limits derived from Biological Variation | N/A |
| Acceptable limits of performance for RIQAS | 15.60% |
| TS & %DEV outside limits | |



| Method | N | Mean | CV% | U _m |
|---------------------------------------|----|---------|------|----------------|
| Beckman DxI 600 / 800 | 13 | 461.623 | 4.6 | 7.42 |
| Active Inhibin A Elisa | 12 | 508.893 | 27.1 | 49.73 |
| Beckman Access | 9 | 443.184 | 4.3 | 7.97 |
| Perkin Elmer DELFIA Xpress/AutoDELFIA | 3 | 636.807 | 16.2 | 74.37 |
| Stat Fax Elisa Readers | 2 | 608.050 | 23.5 | 126.31 |

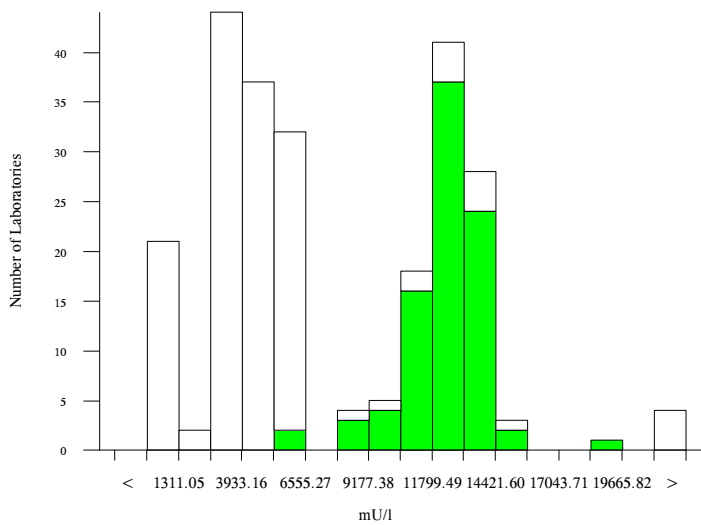


PAPP-A, mU/l

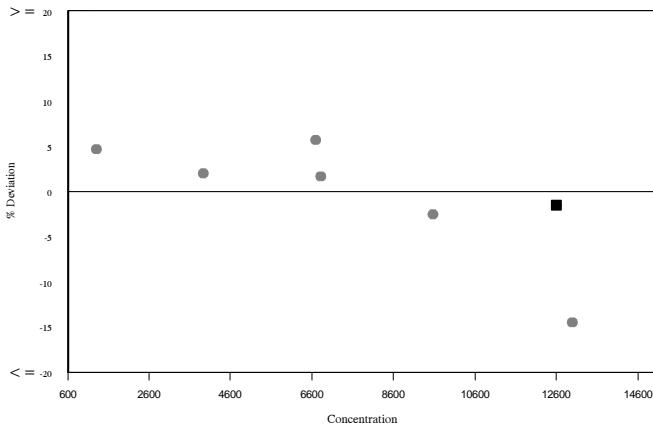
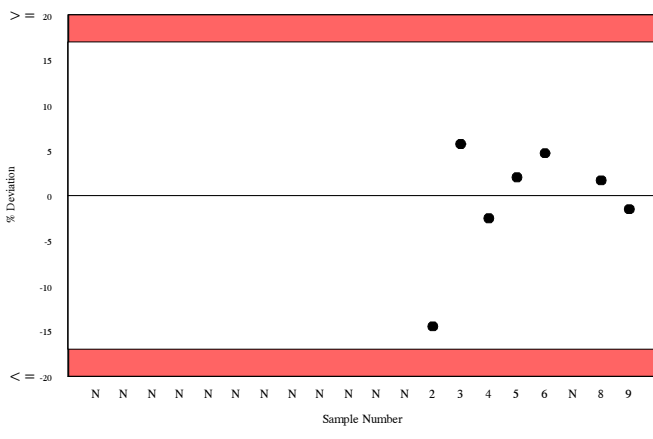
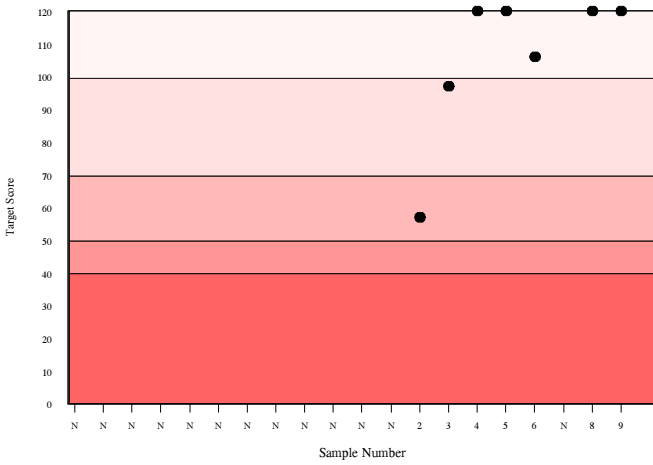
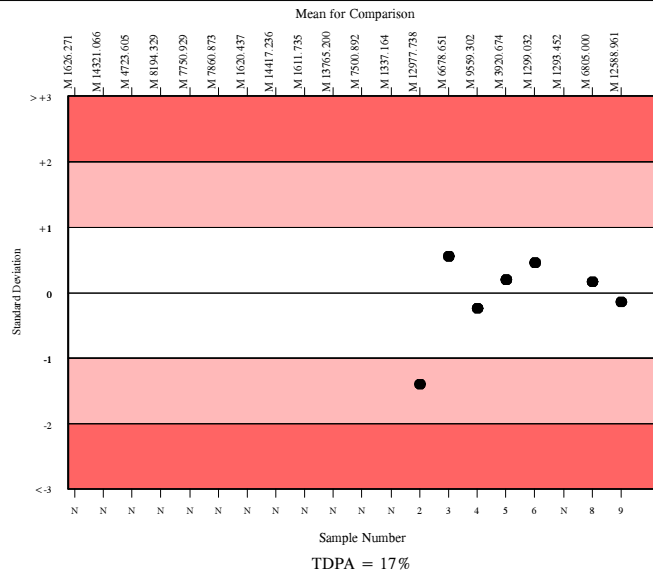
| | N | Mean | CV% | U _m | SDPA | Exc. |
|--------------------------------------------------------------------|-----|-----------|------|----------------|---------|------|
| <input type="checkbox"/> All Methods | 235 | 7430.981 | 60.8 | 368.10 | 851.60a | 7 |
| <input checked="" type="checkbox"/> Siemens/DPC Immulite 2000/2500 | 77 | 12588.961 | 6.8 | 121.80 | 1301.10 | 14 |

| | | | |
|-----------------------|-----------|----------------|------------------|
| ▲ Your Result | 12400.000 | SDI RMSDI | -0.15 Too Few |
| ■ Mean for Comparison | 12588.961 | TS RMTS | 120 Too Few |
| | | %DEV RM%DEV | -1.5 Too Few |

| | |
|-----------------------------------------------------|--------|
| Acceptable limits derived from Biological Variation | 15.1% |
| Acceptable limits of performance for RIQAS | 17.00% |



| Method | N | Mean | CV% | U _m |
|---------------------------------------|----|-----------|------|----------------|
| Siemens/DPC Immulite 2000/2500 | 77 | 12588.961 | 6.8 | 121.80 |
| Perkin Elmer DELFIA Xpress/AutoDELFIA | 37 | 3697.282 | 8.0 | 61.00 |
| Roche Cobas 4000/e411 | 26 | 5284.653 | 6.7 | 86.50 |
| Roche Cobas 6000/8000 | 23 | 5323.521 | 3.7 | 51.80 |
| Beckman DxI 600 / 800 | 14 | 328.213 | 5.7 | 6.20 |
| Brahms, Krytor | 14 | 3803.214 | 6.4 | 81.20 |
| Siemens/DPC Immulite 1000 | 11 | 12756.363 | 11.7 | 561.10 |
| Beckman Access | 5 | 332.218 | 6.3 | 11.70 |

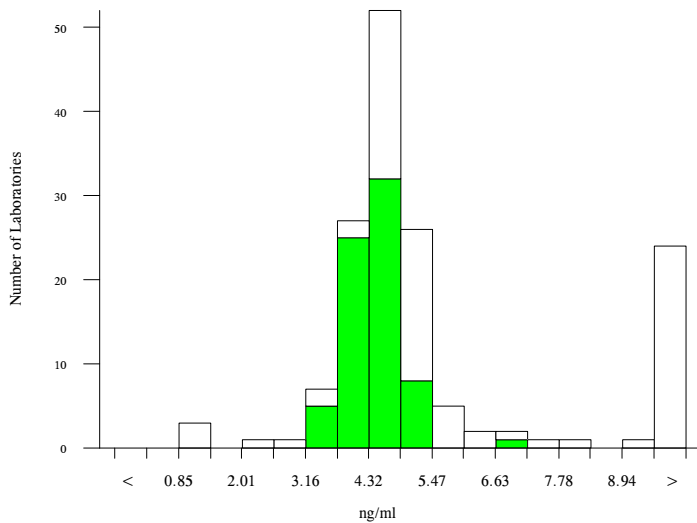


Unconjugated estriol, ng/ml

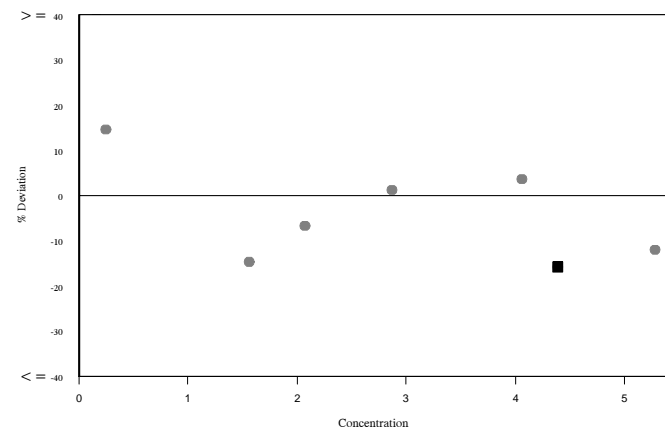
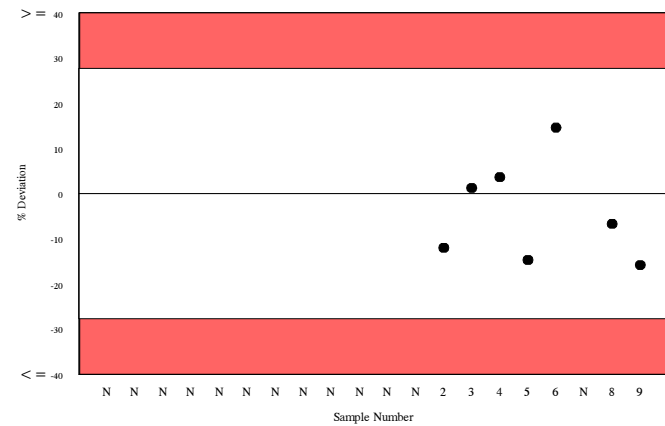
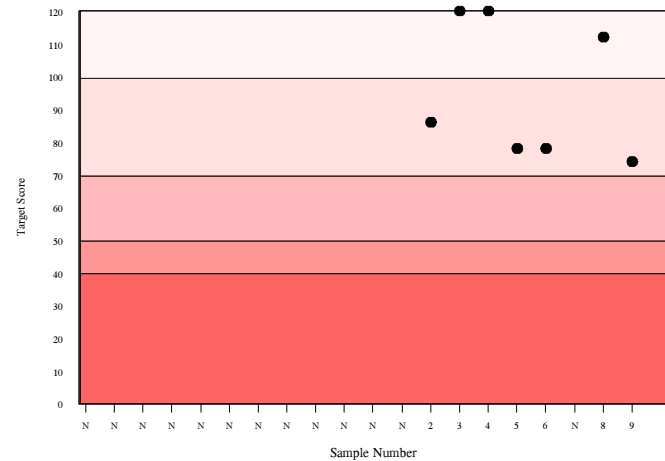
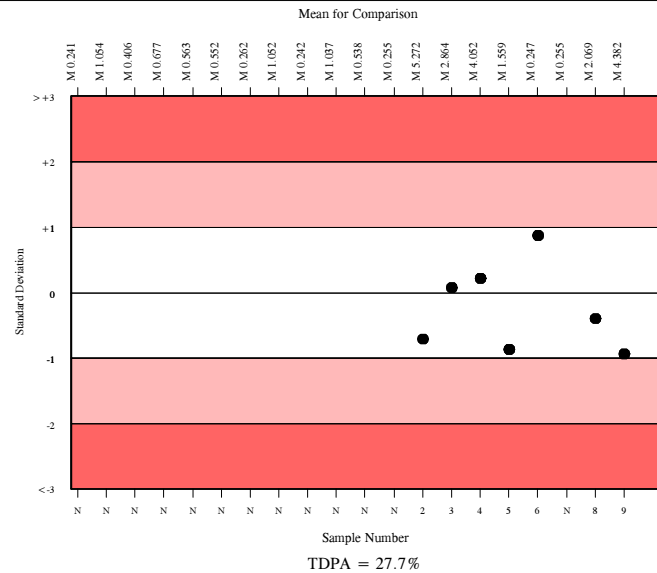
| | N | Mean | CV% | U _m | SDPA | Exc. |
|---------------------------|-----|-------|------|----------------|------|------|
| □ All Methods | 136 | 4.899 | 31.4 | 0.17 | 0.83 | 17 |
| ■ DPC, Immulite 2000/2500 | 68 | 4.382 | 9.2 | 0.06 | 0.74 | 3 |

| | | | |
|-----------------------|-------|--------|---------|
| ▲ Your Result | 3.690 | SDI | -0.94 |
| | | RMSDI | Too Few |
| ■ Mean for Comparison | 4.382 | TS | 74 |
| | | RMTS | Too Few |
| | | %DEV | -15.8 |
| | | RM%DEV | Too Few |

| | |
|-----------------------------------------------------|--------|
| Acceptable limits derived from Biological Variation | N/A |
| Acceptable limits of performance for RIQAS | 27.70% |



| Method | N | Mean | CV% | U _m |
|---------------------------------------|----|--------|------|----------------|
| DPC, Immulite 2000/2500 | 68 | 4.382 | 9.2 | 0.06 |
| Perkin Elmer DELFIA Xpress/AutoDELFIA | 21 | 10.546 | 5.1 | 0.15 |
| Beckman DxI 600 / 800 | 22 | 4.835 | 7.5 | 0.10 |
| DPC, Immulite 1000 | 9 | 4.857 | 5.0 | 0.10 |
| Beckman Access | 10 | 5.260 | 11.6 | 0.24 |
| Brahms, Kryptor | 4 | 2.765 | 34.0 | 0.59 |
| Demeditec ELISA | 2 | 1.350 | 0.0 | 0.00 |
| DRG Elisa | 2 | 6.455 | 5.4 | 0.31 |
| IBL ELISA | 2 | 5.560 | 11.2 | 0.55 |



| Analyte | Mean for Comparison | Your Result | SDI | RMSDI | %DEV | RM%DEV | TS | RMTS | Performance |
|----------------------|---------------------|-------------|-------|---------|--------------|---------|-----------|---------|-------------|
| AFP | 96.934 | 95.500 | -0.20 | Too Few | -1.5 | Too Few | 120 | Too Few | |
| hCG, free beta | 106.678 | 109.000 | 0.20 | Too Few | 2.2 | Too Few | 120 | Too Few | |
| hCG, total | 45.473 | 45.500 | 0.01 | Too Few | 0.1 | Too Few | 120 | Too Few | |
| Inhibin A | 608.050 | 507.000 | -0.73 | Too Few | <u>-16.6</u> | Too Few | <u>47</u> | Too Few | |
| PAPP-A | 12588.961 | 12400.000 | -0.15 | Too Few | -1.5 | Too Few | 120 | Too Few | |
| Unconjugated estriol | 4.382 | 3.690 | -0.94 | Too Few | -15.8 | Too Few | 74 | Too Few | |

ORMSDI N/A

ORM%DEV N/A

ORMTS N/A

END OF REPORT

