

Dena Laboratory

MATERNAL SCREENING

CYCLE 10 SAMPLE 1

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: 2

Issue Date: 20/02/2018

Report re-issued to include authorised late or corrected results

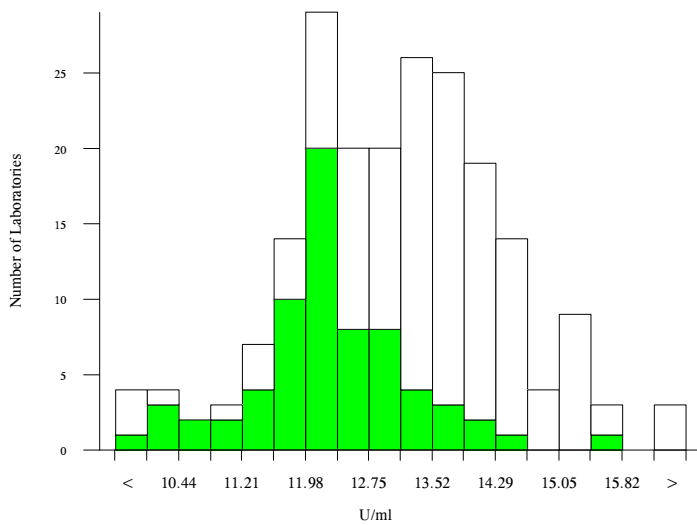
Randox Laboratories Limited
55 Diamond Road
CRUMLIN BT29 4QY
Tel: +44 (0)28 9445 4399
Fax: +44 (0)28 9445 4398
Email: mail@riqas.com

AFP, U/ml

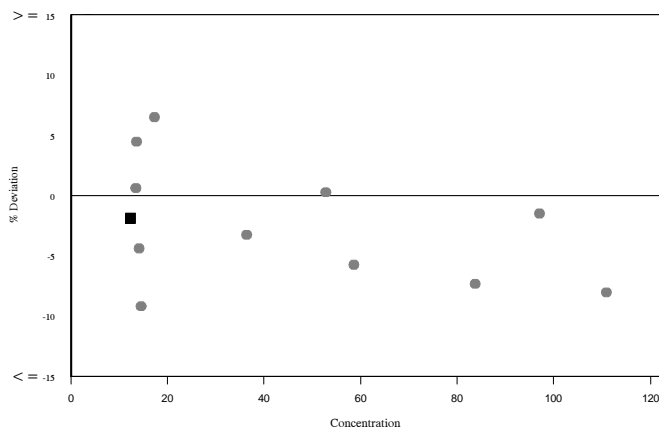
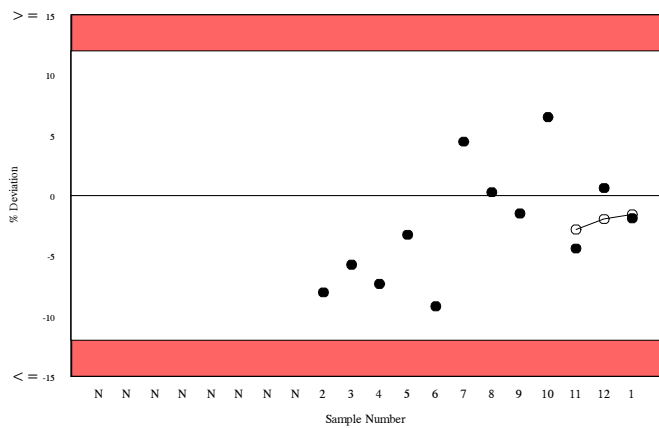
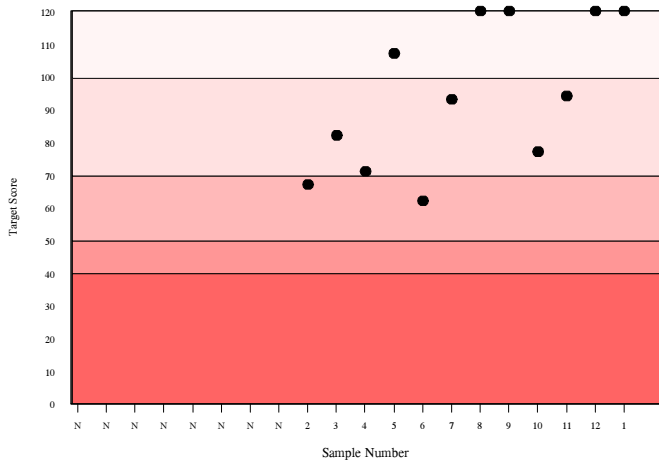
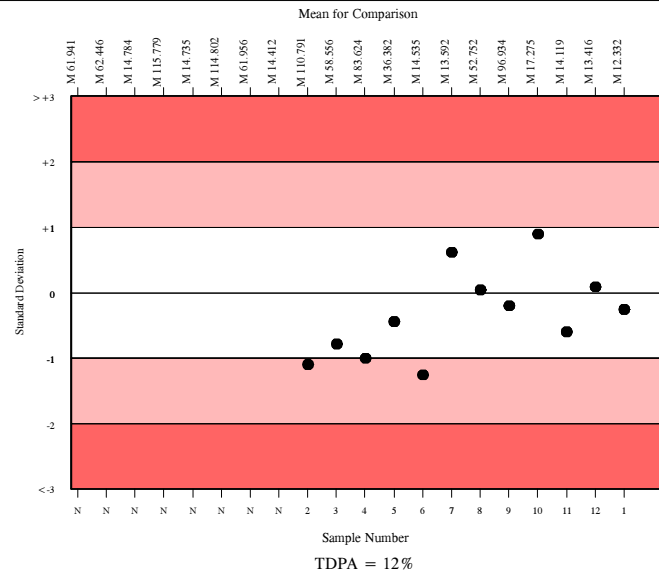
| | N | Mean | CV% | U _m | SDPA | Exc. |
|----------------------------------|-----|--------|-----|----------------|------|------|
| □ All Methods | 173 | 13.138 | 7.8 | 0.10 | 0.96 | 33 |
| ■ Siemens/DPC Immulite 2000/2500 | 57 | 12.332 | 5.6 | 0.12 | 0.90 | 12 |

| | | | |
|-----------------------|--------|----------------|----------------|
| ▲ Your Result | 12.100 | SDI RMSDI | -0.26 -0.21 |
| ■ Mean for Comparison | 12.332 | TS RMTS | 120 98 |
| | | %DEV RM%DEV | -1.9 -1.6 |

| | |
|---|--------|
| 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 | 57 | 12.332 | 5.6 | 0.12 |
| Beckman Dxi 600/800 | 26 | 13.272 | 8.5 | 0.28 |
| Perkin Elmer DELFIA Xpress/AutoDELFIA | 26 | 13.912 | 4.0 | 0.14 |
| Beckman Access/LXi725 | 19 | 13.258 | 6.7 | 0.25 |
| Roche Cobas 6000/8000 | 10 | 13.692 | 1.5 | 0.08 |
| Roche Cobas 4000/e411 | 8 | 13.956 | 5.7 | 0.35 |
| Siemens/DPC Immulite 1000 | 10 | 12.763 | 6.3 | 0.32 |
| Abbott Architect | 2 | 13.050 | 3.9 | 0.45 |
| Siemens Centaur XP/XPT/Classic | 4 | 15.178 | 0.7 | 0.07 |
| Brahms Kryptor | 4 | 12.216 | 4.9 | 0.37 |
| Roche Elecsys | 1 | 13.080 | 0.0 | 0.00 |

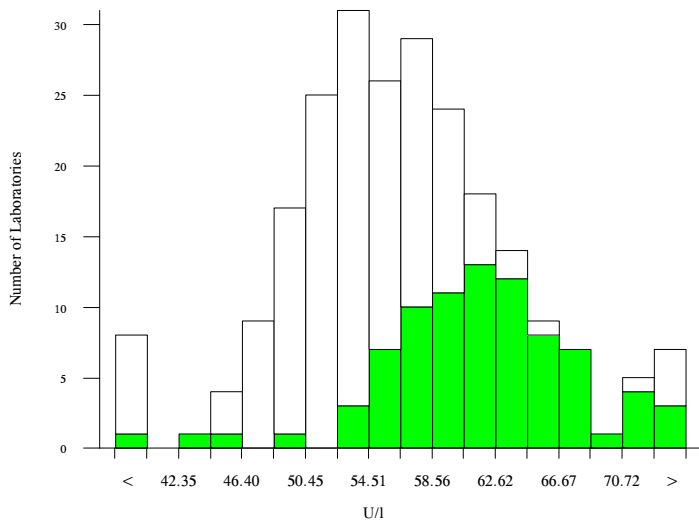


hCG, free beta, U/I

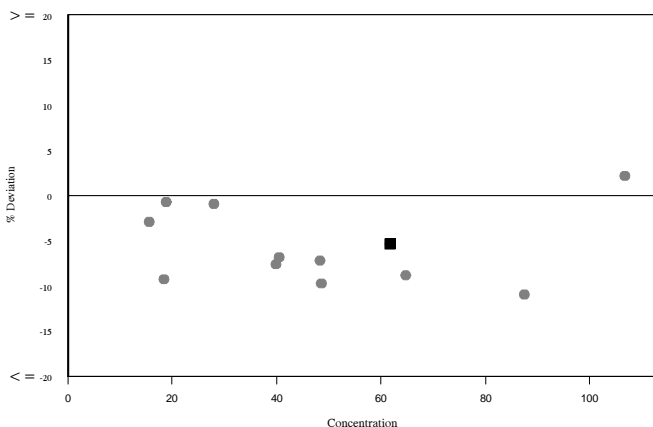
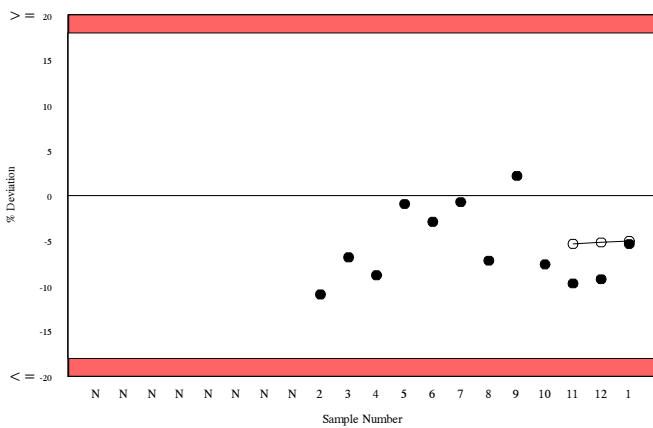
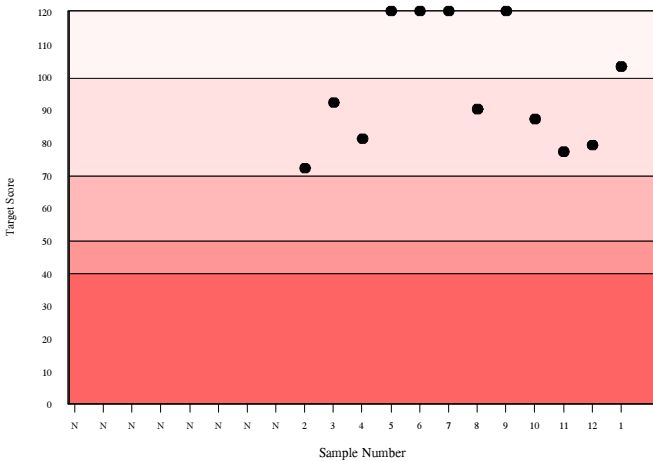
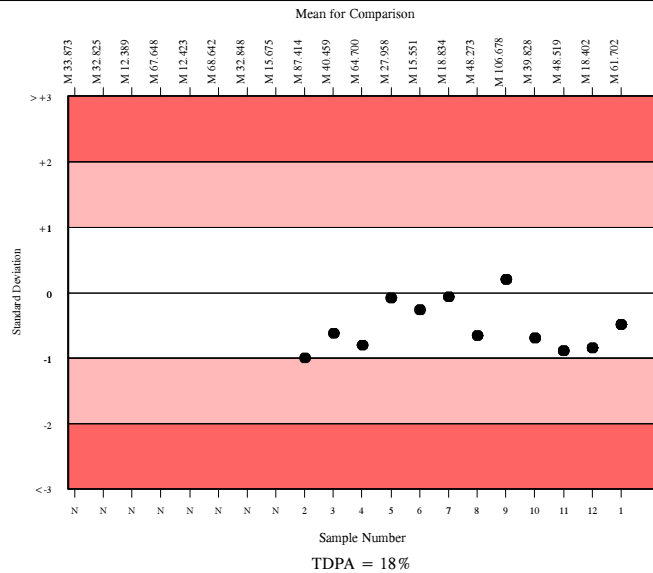
| | N | Mean | CV% | U _m | SDPA | Exc. |
|--------------------------------|-----|--------|-----|----------------|------|------|
| All Methods | 190 | 56.539 | 9.6 | 0.49 | 6.19 | 45 |
| Siemens/DPC Immulite 2000/2500 | 68 | 61.702 | 7.0 | 0.65 | 6.75 | 15 |

| | | | |
|-----------------------|--------|----------------|----------------|
| ▲ Your Result | 58.400 | SDI RMSDI | -0.49 -0.46 |
| ■ Mean for Comparison | 61.702 | TS RMTS | 103 99 |
| | | %DEV RM%DEV | -5.4 -5.0 |

| | |
|---|--------|
| 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 | 68 | 61.702 | 7.0 | 0.65 |
| Perkin Elmer DELFIA Xpress/AutoDELFIA | 36 | 53.127 | 6.6 | 0.74 |
| Roche Cobas 4000/e411 | 31 | 53.537 | 6.6 | 0.79 |
| Roche Cobas 6000/8000 | 26 | 50.997 | 3.2 | 0.40 |
| Brahms, Kryptor | 14 | 58.346 | 3.7 | 0.72 |
| Siemens/DPC Immulite 1000 | 10 | 56.655 | 6.7 | 1.51 |
| Roche Elecsys 2010/1010 | 1 | 63.270 | 0.0 | 0.00 |

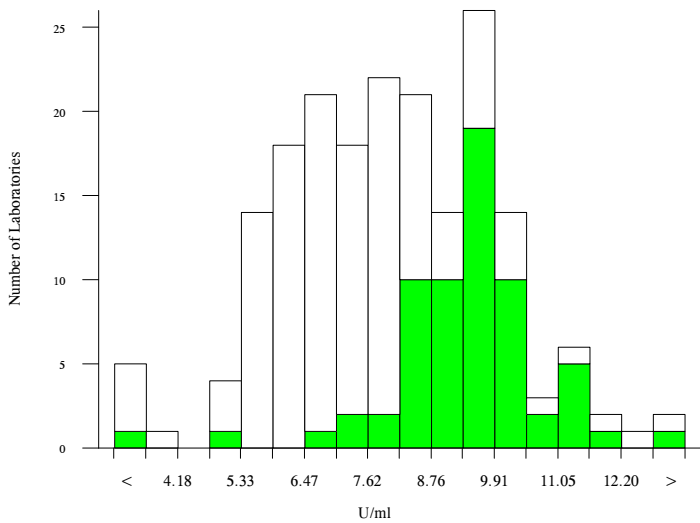


hCG, total, U/ml

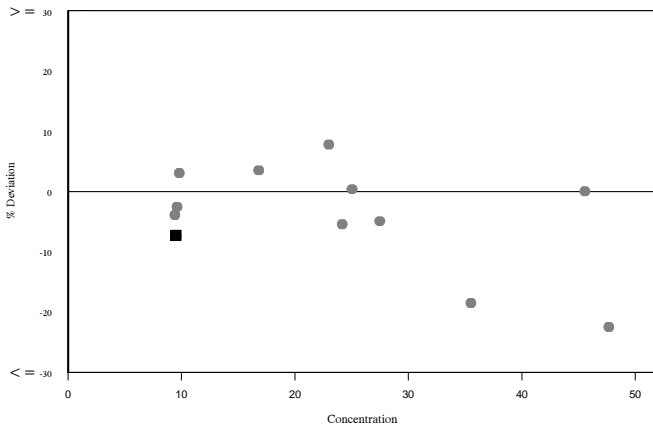
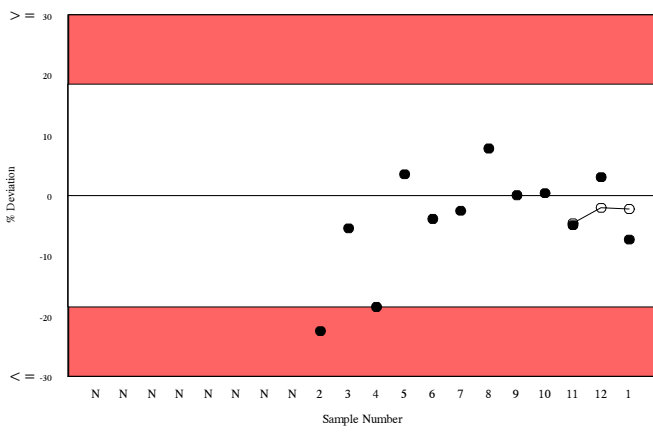
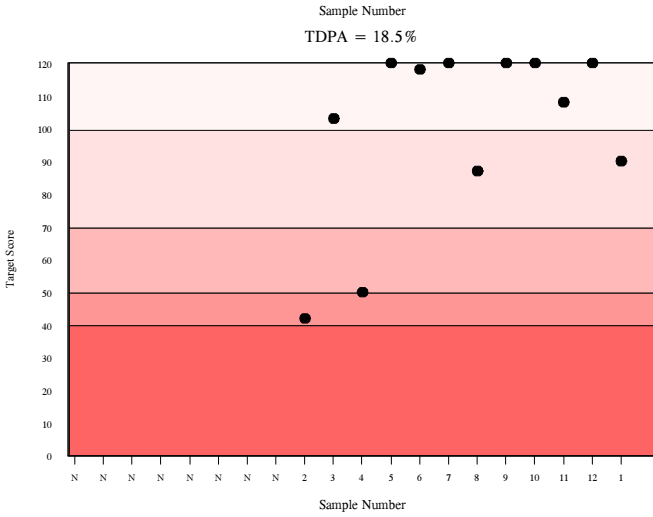
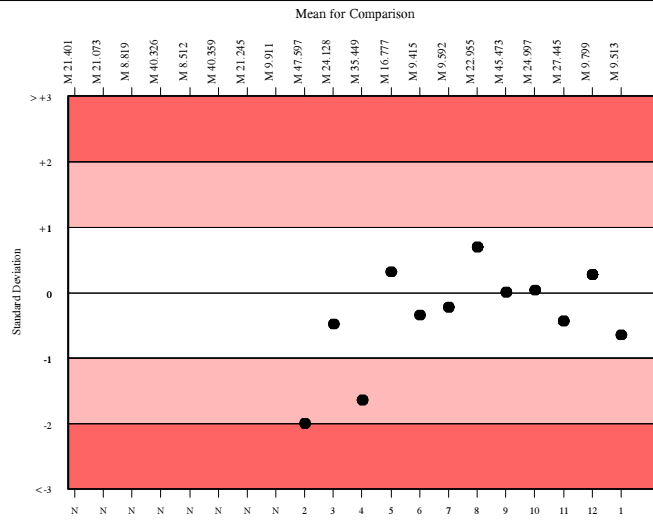
| | N | Mean | CV% | U _m | SDPA | Exc. |
|--------------------------------|-----|-------|------|----------------|------|------|
| All Methods | 162 | 8.195 | 18.6 | 0.15 | 0.92 | 30 |
| Siemens/DPC Immulite 2000/2500 | 56 | 9.513 | 9.5 | 0.15 | 1.07 | 9 |

| | | | |
|-----------------------|-------|--------|-------|
| ▲ Your Result | 8.820 | SDI | -0.65 |
| | | RMSDI | -0.20 |
| ■ Mean for Comparison | 9.513 | TS | 90 |
| | | RMTS | 105 |
| | | %DEV | -7.3 |
| | | RM%DEV | -2.2 |

| | |
|---|--------|
| 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 | 56 | 9.513 | 9.5 | 0.15 |
| Roche hCG + Beta | 21 | 6.342 | 7.2 | 0.12 |
| Beckman DXI Total BhCG (5th IS) | 13 | 7.524 | 11.4 | 0.30 |
| Beckman Access | 15 | 7.783 | 5.2 | 0.13 |
| Siemens/DPC Immulite 1000 | 12 | 10.365 | 9.4 | 0.35 |
| Beckman DxI 600/800 | 9 | 7.955 | 8.2 | 0.27 |
| Beckman Access Total BhCG (5th IS) | 10 | 7.674 | 9.1 | 0.27 |
| Abbott Architect I2000/8200 | 7 | 6.060 | 4.1 | 0.12 |
| Perkin Elmer DELFIA Xpress/AutoDELFIA | 6 | 7.951 | 6.5 | 0.27 |
| Siemens Centaur XP/XPT/Classic | 3 | 5.915 | 9.1 | 0.39 |
| bioMerieux, Vidas/Mini Vidas | 1 | 8.884 | 0.0 | 0.00 |



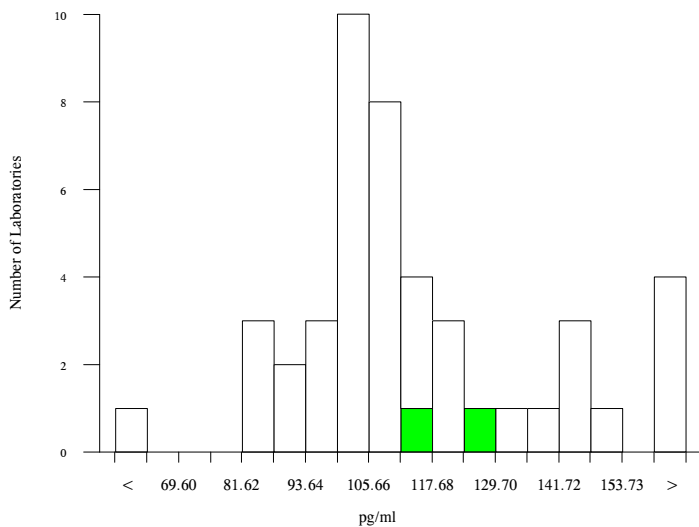
Inhibin A, pg/ml

| | N | Mean | CV% | U _m | SDPA | Exc. |
|--|----|---------|------|----------------|--------|------|
| <input type="checkbox"/> All Methods | 32 | 111.673 | 14.4 | 3.54 | 11.17a | 13 |
| <input checked="" type="checkbox"/> Stat Fax Elisa Readers | 1 | 126.000 | 0.0 | 0.00 | N/A | 1 |

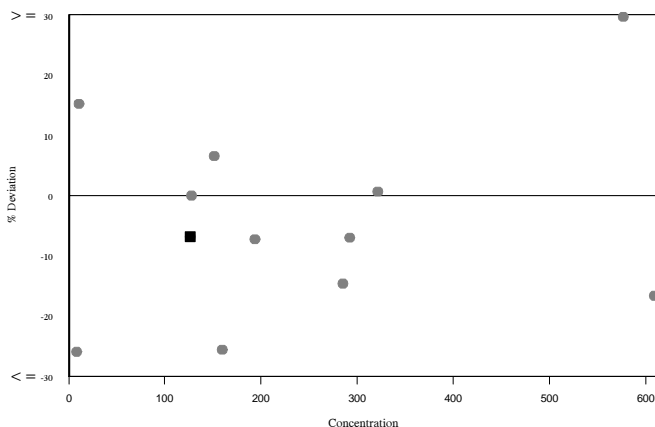
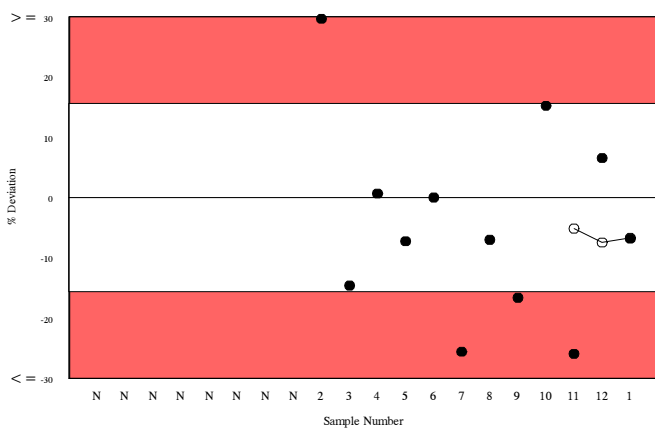
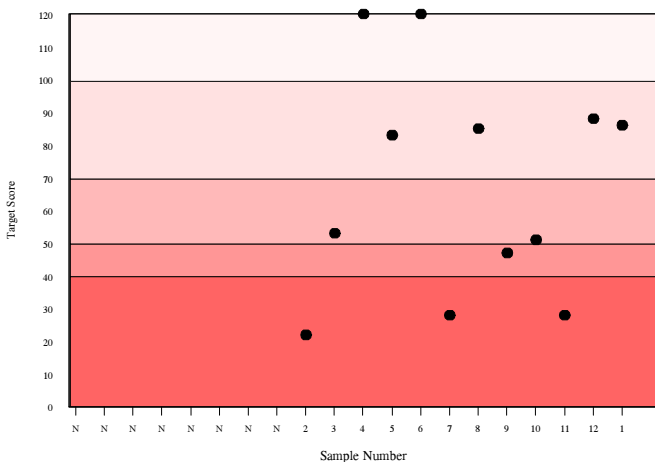
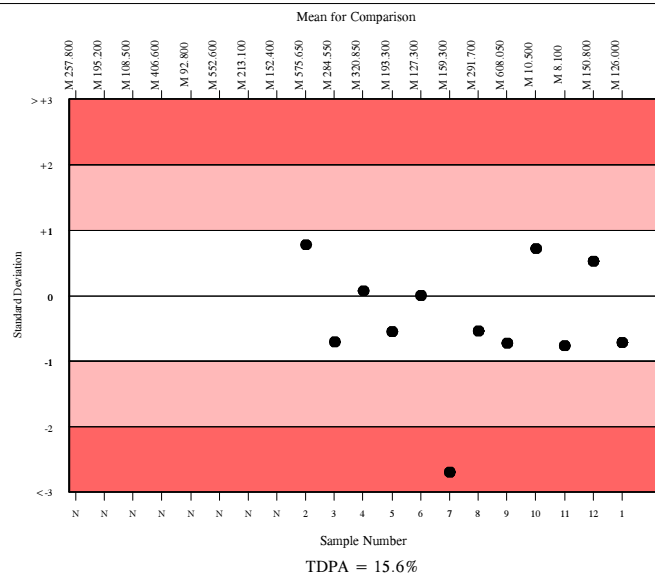
| | | | |
|---|---------|--------|-------|
| <input checked="" type="checkbox"/> Your Result | 117.400 | SDI | -0.72 |
| | | RMSDI | -0.47 |
| <input checked="" type="checkbox"/> Mean for Comparison | 126.000 | TS | 86 |
| | | RMTS | 73 |
| | | %DEV | -6.8 |
| | | RM%DEV | -6.7 |

The mean for comparison is not statistically significant

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



| Method | N | Mean | CV% | U _m |
|---------------------------------------|----|---------|------|----------------|
| Beckman Access | 13 | 101.511 | 5.7 | 2.00 |
| Beckman Dxl 600/800 | 12 | 107.928 | 6.2 | 2.40 |
| ELISA | 5 | 147.273 | 16.5 | 13.56 |
| Beckman Inhibin A Active ELISA | 1 | 141.881 | 0.0 | 0.00 |
| Perkin Elmer DELFIA Xpress/AutoDELFIA | 3 | 154.170 | 8.1 | 9.04 |
| Stat Fax Elisa Readers | 1 | 126.000 | 0.0 | 0.00 |

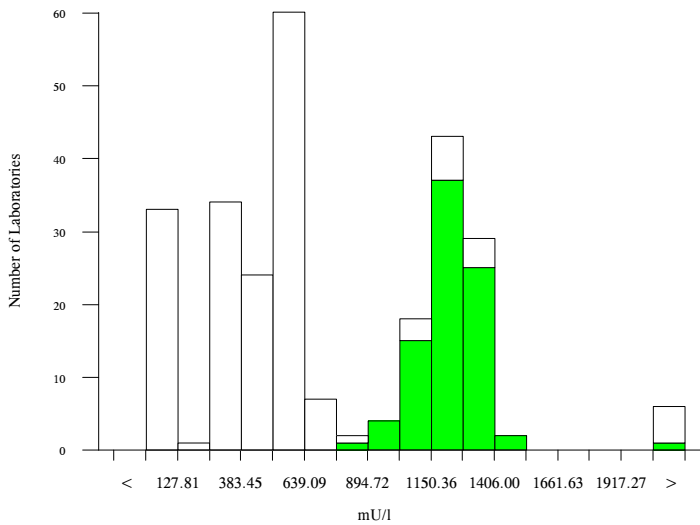


PAPP-A, mU/l

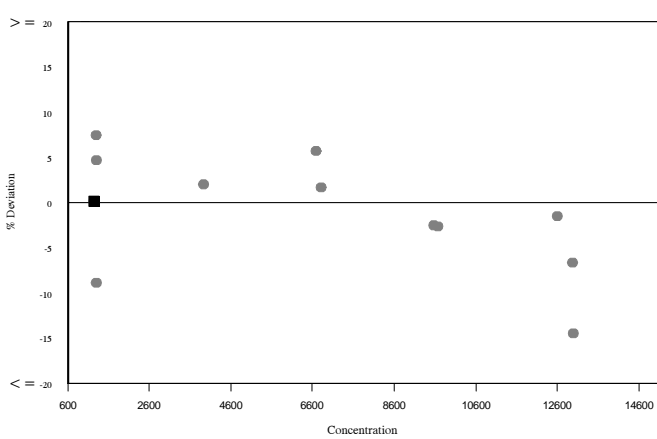
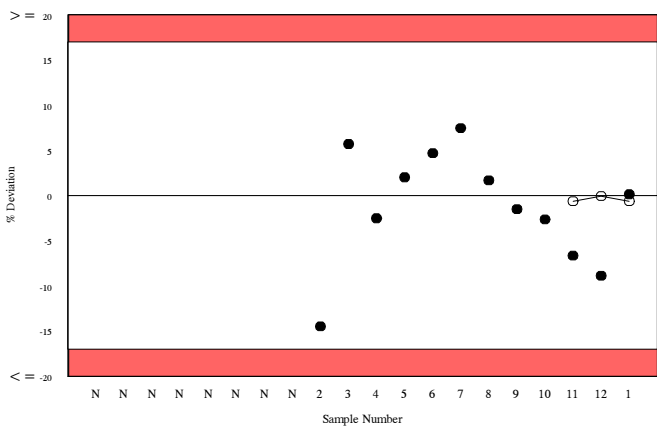
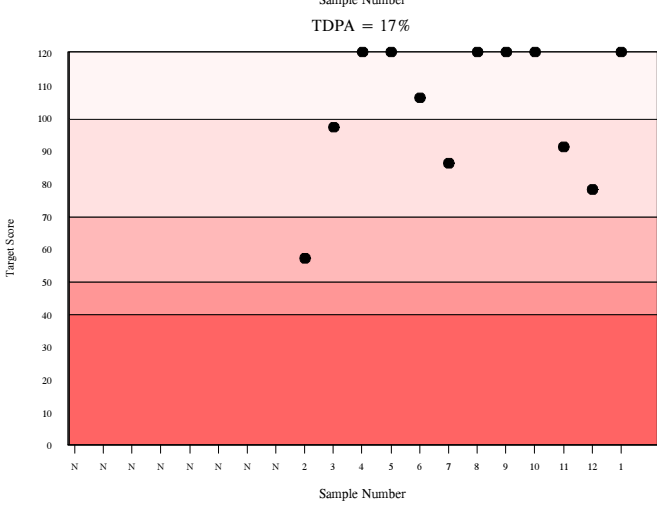
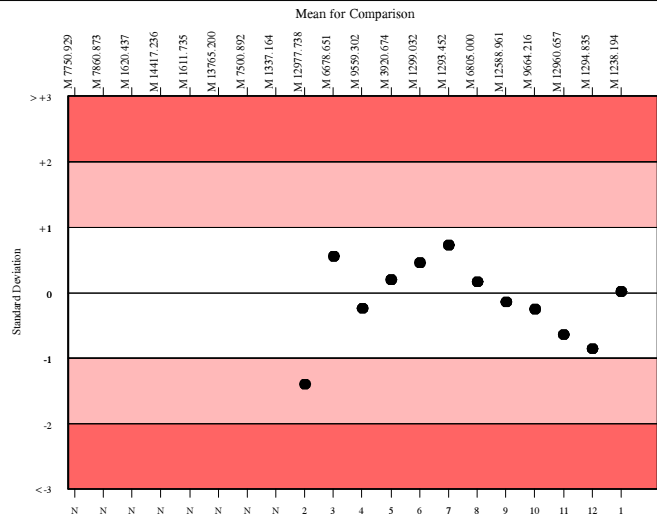
| | N | Mean | CV% | U _m | SDPA | Exc. |
|--------------------------------|-----|----------|------|----------------|--------|------|
| All Methods | 231 | 715.793 | 61.9 | 36.40 | 82.30a | 32 |
| Siemens/DPC Immulite 2000/2500 | 72 | 1238.194 | 7.2 | 13.10 | 127.90 | 13 |

| | | | |
|-----------------------|----------|--------|-------|
| ▲ Your Result | 1240.000 | SDI | 0.01 |
| | | RMSDI | -0.06 |
| ■ Mean for Comparison | 1238.194 | TS | 120 |
| | | RMTS | 108 |
| | | %DEV | 0.1 |
| | | RM%DEV | -0.6 |

| | |
|---|--------|
| 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 | 72 | 1238.194 | 7.2 | 13.10 |
| Perkin Elmer DELFIA Xpress/AutoDELFIA | 31 | 378.774 | 7.5 | 6.30 |
| Roche Cobas 4000/e411 | 27 | 577.185 | 4.6 | 6.30 |
| Roche Cobas 6000/8000 | 29 | 592.649 | 5.6 | 7.70 |
| Beckman DxI 600/800 | 18 | 34.566 | 8.7 | 0.80 |
| Brahms, Kryptor | 13 | 373.323 | 3.9 | 5.00 |
| Beckman Access | 11 | 34.941 | 10.3 | 1.30 |
| Siemens/DPC Immulite 1000 | 8 | 1280.000 | 3.4 | 19.10 |
| Roche Elecsys 2010/1010 | 1 | 1255.000 | 0.0 | 0.00 |

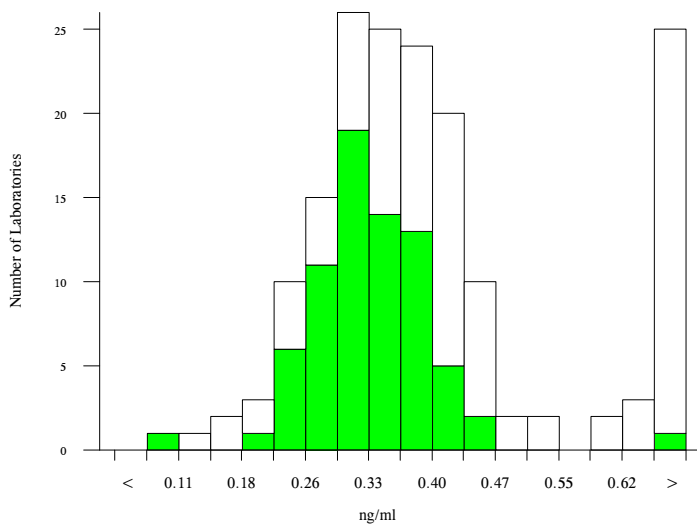


Unconjugated estriol, ng/ml

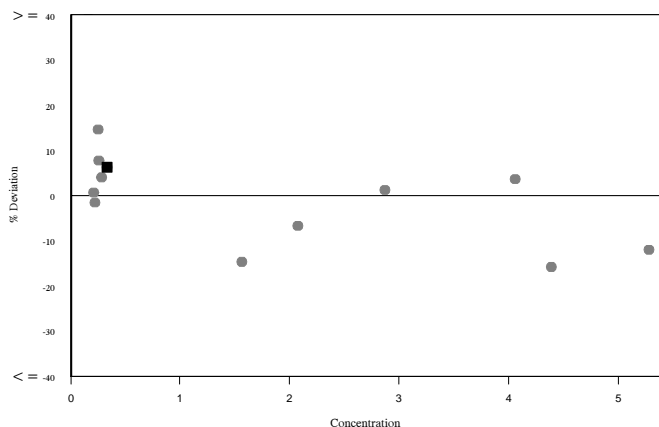
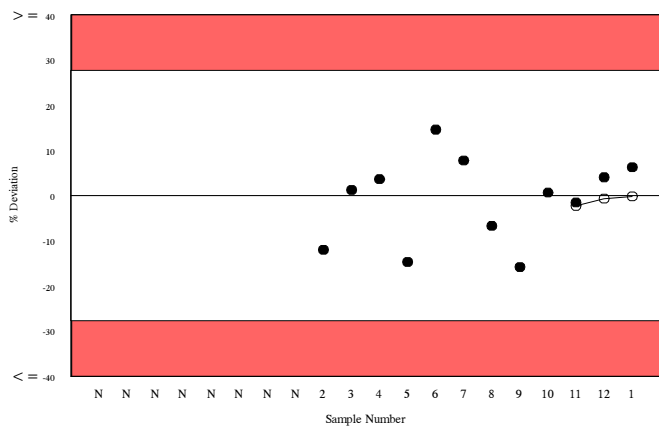
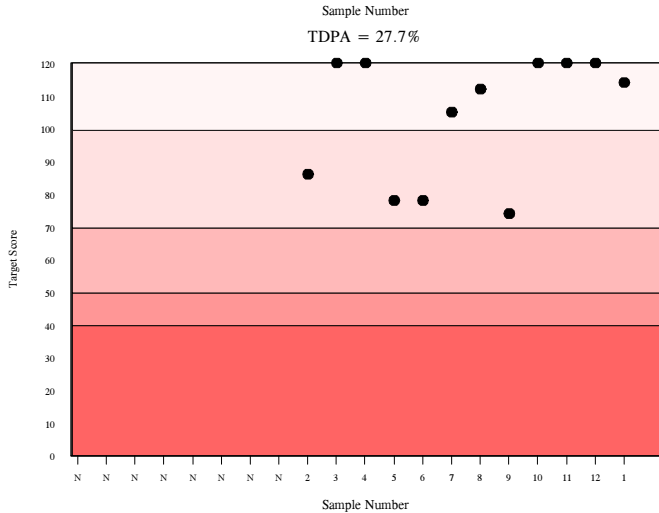
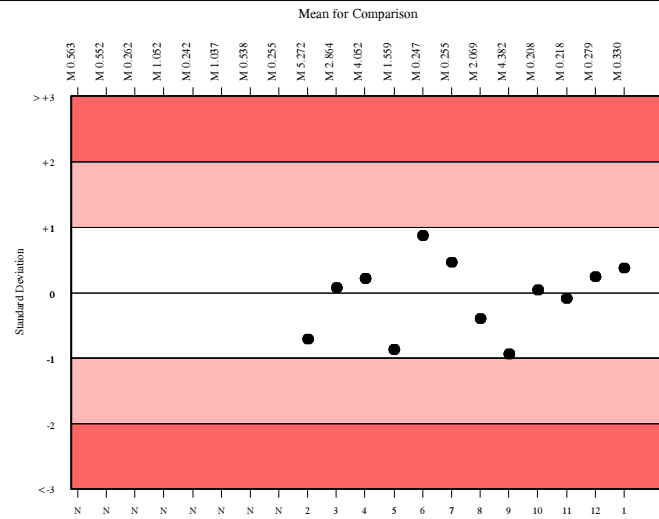
| | N | Mean | CV% | U _m | SDPA | Exc. |
|--------------------------|-----|-------|------|----------------|------|------|
| □ All Methods | 140 | 0.369 | 26.2 | 0.01 | 0.06 | 33 |
| ■ DPC Immulite 2000/2500 | 62 | 0.330 | 14.3 | 0.01 | 0.06 | 12 |

| | | | |
|-----------------------|-------|--------|-------|
| ▲ Your Result | 0.351 | SDI | 0.37 |
| | | RMSDI | -0.01 |
| ■ Mean for Comparison | 0.330 | TS | 114 |
| | | RMTS | 104 |
| | | %DEV | 6.3 |
| | | RM%DEV | -0.2 |

| | |
|---|--------|
| 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 | 62 | 0.330 | 14.3 | 0.01 |
| Beckman Dxi 600/800 | 27 | 0.406 | 13.5 | 0.01 |
| Perkin Elmer DELFIA Xpress/AutoDELFIA | 20 | 0.711 | 7.6 | 0.02 |
| Beckman Access | 20 | 0.412 | 7.6 | 0.01 |
| DPC Immulite 1000 | 9 | 0.292 | 10.7 | 0.01 |
| Brahms, Kryptor | 4 | 0.205 | 11.4 | 0.01 |
| Siemens Centaur XP/XPT/Classic | 2 | 0.333 | 7.4 | 0.02 |



| Analyte | Mean for Comparison | Your Result | SDI | RMSDI | %DEV | RM%DEV | TS | RMTS | Performance |
|----------------------|---------------------|-------------|-------|-------|------|--------|-----|------|-------------|
| AFP | 12.332 | 12.100 | -0.26 | -0.21 | -1.9 | -1.6 | 120 | 98 | |
| hCG, free beta | 61.702 | 58.400 | -0.49 | -0.46 | -5.4 | -5.0 | 103 | 99 | |
| hCG, total | 9.513 | 8.820 | -0.65 | -0.20 | -7.3 | -2.2 | 90 | 105 | |
| Inhibin A | 126.000 | 117.400 | -0.72 | -0.47 | -6.8 | -6.7 | 86 | 73 | |
| PAPP-A | 1238.194 | 1240.000 | 0.01 | -0.06 | 0.1 | -0.6 | 120 | 108 | |
| Unconjugated estriol | 0.330 | 0.351 | 0.37 | -0.01 | 6.3 | -0.2 | 114 | 104 | |

ORMSDI -0.24

ORM%DEV -2.7

ORMTS 98

END OF REPORT

