Pointe Scientific, Inc.
Instrument Applications
Gemstar

GEMSTAR ANALYZER

REAGENT PERFORMANCE GUIDELINES

CHEMICAL#	CHEMISTRY	QC FACTOR LIMITS
15	ALBUMIN	9 - 16
16	TOTAL BILIRUBIN	12 - 19
3	BUN	70 - 150
19	CALCIUM (DRY)	18 - 34
19	CALCIUM (LIQUID)	24 - 40
(33)	CHLORIDE	145 - 185
9	CHOLESTEROL	215 - 500
20	CREATININE	41 - 65
13	GLUCOSE	250 - 310
(35)	MAGNESIUM	10 -15
14	PHOSPHORUS (UV)	20 - 30
17	TOTAL PROTEIN	20 - 30
12	TRIGLYCERIDES	350 - 450
11	URIC ACID	8 - 16

CHEMICAL#	CHEMISTRY	REAGENT DRIFT LIMITS
1	ALK PHOS.	-5 TO +20
(32)	AMYLASE (KIN.)	-5 TO +15
7	CPK	-35 TO +5
2	GGT	-10 TO +10
4	LDH-L	-25 TO +15
5	AST (SGOT)	-10 TO +10
6	ALT (SGPT)	-10 TO +10

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Acid Phos.
Catalog : A7503

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear side aligned front and back.

2. Place the cuvette carrier on its stand.

3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.

4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.

5. Place distilled water in cup 1, controls and sample in cups 2 through 12 of the sample cup rack.

6. Using the GEMSTAR pipettor with 50ul pipettes, aspirate sample into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.

7. Check that the GEMSTAR temperature light is on.

8. An open channel must be used for AcP: example No. 33.

9. Press CONTINUE and enter the following parameters:

1. TC	7
3. UNITS (mg/dl)	2
4. DEC. PT.	1
6. INC. 1 (SEC)	360
7. INC. 2 (SEC)	60
8. DIR	1
9. FW POS 1	5
11. FIRST READ (SEC)	300
12. DELTA T (SEC)	180
16. AUX. LIM.	2.00
17. FACTOR	288
20. MAX. PRT.	30.0

10.Press the RUN key. ID will appear on the display.

10. Enter the RUN identification number. Press CONTINUE.

11. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.

12. Quickly remove the pipettor and close the door. Immediately press the RUN key.

    NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

13. In approximately 8 minutes, the AcP assay will be completed and the results printed in U/L.

EXPECTED VALUES:
Serum Total Acid Phos.: 0 – 9 U/L (37^{o}C)
Serum Prostatic Acid Phos.: 0 – 3 U/L (37^{o}C)

Serum Prostatic Acid Phosphatase (U/L) =
Total Acid Phosphatase (U/L) –Non-Prostatic Acid Phosphatase (U/L)

When Acid Phosphatase values exceed 30 U/L, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Albumin
Catalog : A7502

REAGENT PREPARATION: Reagent is ready to use.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear side aligned front and back.
2. Place the cuvette carrier on its stand.
3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.
4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.
5. Place distilled water in cup 1, Albumin standard or calibrator in cups 2 , and samples in cups 3 through 12 of the sample cup rack.
6. Using the GEMSTAR pipettor with 10ul pipettes, aspirate sample into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.
7. Check that the GEMSTAR temperature light is on.
8. Enter CHEMISTRY 15, C15 will appear on the display.
9. Enter the standard concentration by pressing the STD key.
10. Pres the CONTINUE key, FINI will appear on the display.
11. Enter CHEMISTRY 15, C15 will appear on the display.
12. Press the RUN key. ID will appear on the display.
13. Enter the RUN identification number. Press CONTINUE.
14. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded

    pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.
15. Quickly remove the pipettor and close the door. Immediately press the RUN key.

    NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.
16. In approximately 1 minute, the Albumin assay will be completed and the results printed.

    EXPECTED VALUES:
    3.5 – 5.3 mg/dl

    When Albumin values exceed 6.0 mg/dl, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

    QC Factor Limits: 2 - 6

    Rev. 6/01

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Alk. Phos.
Catalog : A7505

REAGENT PREPARATION: Reconstitute each vial according to package insert instructions.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear side aligned front and back.
2. Place the cuvette carrier on its stand.
3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.
4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.
5. Check that the GEMSTAR temperature light is on.
6. Enter CHEMISTRY 1, C1 will appear on the display.
7. Press the RUN key. ID will appear on the display.
8. Enter the RUN identification number. Press CONTINUE.
9. Place distilled water in cup 1 and controls and samples in cups 2 through 12 of the sample cup rack.
10. Using the GEMSTAR pipettor with 10ul pipettes, aspirate samples into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.
11. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.
12. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

13. In approximately 3 minutes, the AP assay will be completed and the results printed in U/L at 37^{o}C.

EXPECTED VALUES:
35 – 123 U/L (37^{o}C)

When AP values exceed 800 U/L, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

Reagent Drift Limits: -5 to +20

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: ALT (SGPT)
Catalog : A7525

REAGENT PREPARATION: Reconstitute each vial according to package insert instructions.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear side aligned front and back.
2. Place the cuvette carrier on its stand.
3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.
4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.
5. Check that the GEMSTAR temperature light is on.
6. Enter CHEMISTRY 6, C6 will appear on the display.
7. Press the RUN key. ID will appear on the display.
8. Enter the RUN identification number. Press CONTINUE.
9. Place distilled water in cup 1 and controls and samples in cups 2 through 12 of the sample cup rack.
10. Using the GEMSTAR pipettor with 50 ul pipettes, aspirate samples into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.
11. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.
12. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

13. In approximately 5 minutes, the AST assay will be completed and the results printed in U/L at 37^{o}C.

EXPECTED VALUES:
Up to 38 U/L

When ALT values exceed 500 U/L, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

Reagent Drift Limits: -10 to +10

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Amylase
Catalog : A7564

REAGENT PREPARATION: Reagent supplied as a ready to use liquid.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear side aligned front and back.

2. Place the cuvette carrier on its stand.

3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.

4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.

5. Place distilled water in cup 1, controls and samples in cups 2 through 12 of the sample cup rack.

6. Using the GEMSTAR pipettor with 10 ul pipettes, aspirate samples into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.

7. Check that the GEMSTAR temperature light is on.

8. An open channel must be used for Amylase: example No. 32.

9. Press CONTINUE and enter the following parameters:

1. TC	6
3. UNITS (mg/dl)	2
4. DEC. PT.	0
5. # OF READS	16
6. INC. 1 (SEC)	360
7. INC. 2 (SEC)	60
8. DIR	1
9. FW POS 1	5
11. FIRST READ (SEC)	30
12. DELTA T (SEC)	15
14. SEC. SIZE	.100
15. SEOE x 1000	5.000
16. AUX. LIM.	2.000
17. FACTOR	5504
20. MAX. PRT.	2000

10. Press the RUN key. ID will appear on the display.

11. Enter the RUN identification number. Press CONTINUE.

12. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.

13. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

14. In approximately 2 minutes, the Amylase assay will be completed and the results printed in U/L.

EXPECTED VALUES:
Serum: 25 – 125 U/L (37^{o}C)
Urine: 0 – 14 U/Hour (37^{o}C)

When Amylase values exceed 2000 U/L, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

Reagent Drift Limits: -10 to +10

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: AST (SGOT)
Catalog : A7560

REAGENT PREPARATION: Reconstitute each vial according to package insert instructions.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear side aligned front and back.
2. Place the cuvette carrier on its stand.
3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.
4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.
5. Check that the GEMSTAR temperature light is on.
6. Enter CHEMISTRY 5, C5 will appear on the display.
7. Press the RUN key. ID will appear on the display.
8. Enter the RUN identification number. Press CONTINUE.
9. Place distilled water in cup 1 and controls and samples in cups 2 through 12 of the sample cup rack.
10. Using the GEMSTAR pipettor with 50 ul pipettes, aspirate samples into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.
11. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.
12. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

13. In approximately 5 minutes, the AST assay will be completed and the results printed in U/L at 37°C.

EXPECTED VALUES:
Up to 40 U/L at (37°C)

When AST values exceed 500 U/L, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

Reagent Drift Limits: -10 to +10

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: BUN
Catalog : B7550

REAGENT PREPARATION: Reconstitute each vial according to package insert instructions.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear sides aligned front and back.
2. Place the cuvette carrier on its stand.
3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.
4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.
5. Place distilled water in cup 1, BUN standard in cup 2, and samples in cups 3 through 12 of the sample cup rack.
6. Using the GEMSTAR pipettor with 10ul pipettes, aspirate samples into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.
7. Check that the GEMSTAR temperature light is on.
8. Enter CHEMISTRY 3, C3 will appear on the display.
9. Enter the standard concentration by pressing the STD key.
10. Press the CONTINUE key, FINI will appear on the display.
11. Enter CHEMISTRY 3, C3 will appear on the display.
12. Press the RUN key. ID will appear on the display.
13. Enter the RUN identification number. Press CONTINUE.
14. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.
15. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

16. In approximately 1 minute, the BUN assay will be completed and the results printed in mg/dl.

EXPECTED VALUES:
Serum/Plasma 7 – 18 mg/dl

When BUN values exceed 50 mg/dl, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

QC Factor Limits: 70 - 150

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Calcium (Dry)
Catalog : C7508

REAGENT PREPARATION: Reconstitute each vial according to package insert instructions.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear sides aligned front and back.
2. Place the cuvette carrier on its stand.
3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.
4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.
5. Place distilled water in cup 1, Calcium standard or calibrator in cup 2, and samples in cups 3 through 12 of the sample cup rack.
6. Using the GEMSTAR pipettor with 10ul pipettes, aspirate samples into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.
7. Check that the GEMSTAR temperature light is on.
8. Enter CHEMISTRY 19, C19 will appear on the display.
9. Enter the standard concentration by pressing the STD key.
10. Press the CONTINUE key, FINI will appear on the display.
11. Enter CHEMISTRY 19, C19 will appear on the display.
12. Press the RUN key. ID will appear on the display.
13. Enter the RUN identification number. Press CONTINUE.
14. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.
15. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

16. In approximately 10 minutes, the Calcium assay will be completed and the results printed.

EXPECTED VALUES:
8.5 – 10.5 mg/dl

When Calcium values exceed 15.0 mg/dl, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

QC Factor Limits: 18 - 34

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Calcium (Liquid)
Catalog : C7503

REAGENT PREPARATION: Prepare working reagent by mixing equal volumes of Calcium Color Reagent and Calcium Buffer Reagent.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear sides aligned front and back.
2. Place the cuvette carrier on its stand.
3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.
4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.
5. Place distilled water in cup 1, Calcium standard or calibrator in cup 2, and samples in cups 3 through 12 of the sample cup rack.
6. Using the GEMSTAR pipettor with 10ul pipettes, aspirate samples into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.
7. Check that the GEMSTAR temperature light is on.
8. Enter CHEMISTRY 19, C19 will appear on the display.
9. Enter the standard concentration by pressing the STD key.
10. Press the CONTINUE key, FINI will appear on the display.
11. Enter CHEMISTRY 19, C19 will appear on the display.
12. Press the RUN key. ID will appear on the display.
13. Enter the RUN identification number. Press CONTINUE.
14. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.
15. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

16. In approximately 10 minutes, the Calcium assay will be completed and the results printed.

EXPECTED VALUES:
8.5 – 10.5 mg/dl

When Calcium values exceed 15.0 mg/dl, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

QC Factor Limits: 24 - 40

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Carbon Dioxide
Catalog : C7504

REAGENT PREPARATION: Reconstitute each vial according to package insert instructions.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear sides aligned front and back.

2. Place the cuvette carrier on its stand.

3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.

4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.

5. Place distilled water in cup 1, Carbon Dioxide standard or calibrator in cup 2, and samples in cups 3 through 12 of the sample cup rack.

6. Using the GEMSTAR pipettor with 10ul pipettes, aspirate samples into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.

7. Check that the GEMSTAR temperature light is on.

8. An open channel must be used for Carbon Dioxide, for example: No. 39.

9. Press CONTINUE and enter the following parameters:

1. TC	1
2. TEMP (^{o}C)	37
3. UNITS (mg/dl)	5
4. DEC. PT.	0
5. # OF READS	1
6. INC. 1 (SEC)	240
7. INC. 2 (SEC)	60
8. DIR	1
9. FW POS 1	2
10. FW POS 2	0
11. FIRST READ (SEC)	300
12. DELTA T (SEC)	0
13. REF READ	0.000
14. SEC. SIZE	0.000
15. SEOE X 1000	0.000
16. AUX. LIM.	2.000
17. FACTOR	0.0
18. MAX. DELTA ABS	0.000
19. MIN. RGT. ABS.	0.000
20. MAX. PRT.	40

10. Enter the standard concentration by pressing the STD key.

11. Press the CONTINUE key, FINI will appear on the display.

12. Enter CHEMISTRY #, ID will appear on the display. Press RUN.

13. Enter the RUN identification number. Press CONTINUE.

14. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.

15. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

16. In approximately 6 minutes, the Carbon Dioxide assay will be completed and the results printed.

EXPECTED VALUES:
23 – 34 mEq/dL

When Carbon Dioxide values exceed 40 mEq/L, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Chloride
Catalog : C7501

REAGENT PREPARATION: Reagent is ready to use.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear sides aligned front and back.

2. Place the cuvette carrier on its stand.

3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.

4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.

5. Place distilled water in cup 1, Chloride standard or calibrator in cup 2, and samples in cups 3 through 12 of the sample cup rack.

6. Using the GEMSTAR pipettor with 10ul pipettes, aspirate samples into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.

7. Check that the GEMSTAR temperature light is on.

8. An open channel must be used for Chloride: for example: No. 33.

9. Press CONTINUE and enter the following parameters:

1. TC	1
2. TEMP (^{o}C)	37
3. UNITS (mg/dl)	5
4. DEC. PT.	0
5. # OF READS	1
6. INC. 1 (SEC)	60
7. INC. 2 (SEC)	60
8. DIR	1
9. FW POS 1	6
10. FW POS 2	0
11. FIRST READ (SEC)	60
12. DELTA T (SEC)	0
13. REF READ	0.000
14. SEC. SIZE	0.000
15. SEOE X 1000	0.000
16. AUX. LIM.	2.000
17. FACTOR	0.0
18. MAX. DELTA ABS	0.000
19. MIN. RGT. ABS.	0.000
20. MAX. PRT.	120

10. Enter the standard concentration by pressing the STD key.

11. Press the CONTINUE key, FINI will appear on the display.

12. Enter CHEMISTRY #, ID will appear on the display. Press RUN.

13. Enter the RUN identification number. Press CONTINUE.

14. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.

15. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

16. In approximately 1 minute, the Chloride assay will be completed and the results printed in mEq/L.

EXPECTED VALUES:
Serum 98 – 106 mEq/L

When Chloride values exceed 120 mEq/L, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

QC Factor Limits: 145 - 185

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Cholesterol
Catalog : C7509

REAGENT PREPARATION: Reconstitute each vial according to package insert instructions.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear sides aligned front and back.
2. Place the cuvette carrier on its stand.
3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.
4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.
5. Place distilled water in cup 1, Cholesterol standard in cup 2, and samples in cups 3 through 12 of the sample cup rack.
6. Using the GEMSTAR pipettor with 10ul pipettes, aspirate samples into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.
7. Check that the GEMSTAR temperature light is on.
8. Enter CHEMISTRY 9, C9 will appear on the display.
9. Enter the standard concentration by pressing the STD key.
10. Press the CONTINUE key, FINI will appear on the display.
11. Enter CHEMISTRY 9, C9 will appear on the display.
12. Press the RUN key. ID will appear on the display.
13. Enter the RUN identification number. Press CONTINUE.
14. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.
15. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

16. In approximately 10 minutes, the Cholesterol assay will be completed and the results printed in mEq/L.

EXPECTED VALUES:
Desirable Cholesterol <200 mg/dl
Borderline High Cholesterol 200 – 239 mg/dl
High Cholesterol >240 mg/dl

When Cholesterol values exceed 500 mg/dl, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

QC Factor Limits: 345 - 500

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: CK
Catalog : C7512

REAGENT PREPARATION: Reconstitute each vial according to package insert instructions.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear sides aligned front and back.
2. Place the cuvette carrier on its stand.
3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.
4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.
5. Check that the GEMSTAR temperature light is on.
6. Enter CHEMISTRY 7, C7 will appear on the display.
7. Press the RUN key. ID will appear on the display.
8. Enter the RUN identification number. Press CONTINUE.
9. Place distilled water in cup 1 and controls and samples in cups 2 through 12 of the sample cup rack.
10. Using the GEMSTAR pipettor with 10ul pipettes, aspirate samples into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.
11. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.
12. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

13. In approximately 4 minutes, the CK assay will be completed ad the results printed in U/L at 37^{o}C.

EXPECTED VALUES:
25 – 192 U/L (37^{o}C)

When CK values exceed 1000 U/L, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

Reagent Drift Limit: -35 to +5

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Creatinine
Catalog : C7539

REAGENT PREPARATION: Prepare working reagent by mixing Picric Acid and Sodium Hydroxide Reagents according to package insert instructions.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear sides aligned front and back.
2. Place the cuvette carrier on its stand.
3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.
4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.
5. Place distilled water in cup 1, Creatinine standard or calibrator in cup 2, and samples in cups 3 through12 of the sample cup rack.
6. Using the GEMSTAR pipettor with 10ul pipettes, aspirate samples into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.
7. Check that the GEMSTAR temperature light is on.
8. Enter CHEMISTRY 20, C20 will appear on the display.
9. Enter the standard concentration by pressing the STD key.
10. Press the CONTINUE key, FINI will appear on the display.
11. Enter CHEMISTRY 20, C20 will appear on the display.
12. Press the RUN key. ID will appear on the display.
13. Enter the RUN identification number. Press CONTINUE.
14. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.
15. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

16. In approximately 1.5 minutes, the Creatinine assay will be completed ad the results printed.

EXPECTED VALUES:
0.4 – 1.4 mg/dl

When Creatinine values exceed 15.0 mg/dl, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

QC Factor Limits: 41 - 65

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Direct Bilirubin
Catalog : B7538

REAGENT PREPARATION: Prepare working reagent by adding 5ul (0.005ml) of Direct Bilirubin Nitrite Reagent per 1.0ml (or 50ul/10ml reagent) of Direct Bilirubin Reagent.

PROCEDURE: (Test Run)

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear side aligned front and back.
2. Place the cuvette carrier on its stand.
3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.
4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.
5. Check that the GEMSTAR temperature light is on.
6. Enter CHEMISTRY 21, C21 will appear on the display.
7. Press the RUN key. ID will appear on the display.
8. Enter the RUN identification number. Press CONTINUE.
9. Place distilled water in cup 1 and controls and samples in cups 2 through 12 of the sample cup rack.
10. Using the GEMSTAR pipettor with 50 ul pipettes, aspirate samples into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.
11. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.
12. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

13. In approximately 1 minute, the Direct Bilirubin Test assay will be completed and the results printed in mg/dl.

PROCEDURE: (Blank Run)

1. Repeat steps 1 through 11 of Direct Bilirubin test procedure but use Direct Bilirubin Reagent without Nitrite.
2. At the end of the run, the results of the Direct Bilirubin sample blank will be printed in mg/dl. This result must be subtracted from the test run to obtain the Direct Bilirubin results.

EXPECTED VALUES:
Adults 0 – 0.3 mg/dl

When Direct Bilirubin values exceed 10 mg/dl, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: GGT (Soluble)
Catalog : G7570

REAGENT PREPARATION: Reconstitute each vial according to package insert instructions.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear sides aligned front and back.

2. Place the cuvette carrier on its stand.

3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.

4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.

5. Place distilled water in cup 1, controls and samples in cups 2 through 12 of the sample cup rack.

6. Using the GEMSTAR pipettor with 10ul pipettes, aspirate samples into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.

7. Check that the GEMSTAR temperature light is on.

8. An open channel must be used for GGT: example No. 32.

9. Press CONTINUE and enter the following parameters:

1. TC	6
3. UNITS (mg/dl)	2
4. DEC. PT.	0
5. # OF READS	16
6. INC. 1 (SEC)	360
7. INC. 2 (SEC)	60
8. DIR	1
9. FW POS 1	5
11. FIRST READ (SEC)	30
12. DELTA T (SEC)	15
14. SEC. SIZE	.100
15. SEOE X 1000	5.000
16. AUX. LIM.	2.000
17. FACTOR	7474
20. MAX. PRT.	1000

10. Press the RUN key. ID will appear on the display.

11. Enter the RUN identification number. Press CONTINUE.

12. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.

13. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

14. In approximately 2 minutes, the GGT assay will be completed ad the results printed in U/L.

EXPECTED VALUES:
Serum: 5 – 54 U/L (37°C)

When GGT values exceed 1000 U/L, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

Reagent Drift Limits: -10 to +10

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Glucose Hex.
Catalog : G7518

REAGENT PREPARATION: Reconstitute each vial according to package insert instructions.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear sides aligned front and back.
2. Place the cuvette carrier on its stand.
3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.
4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.
5. Place distilled water in cup 1, Glucose standard in cup 2, and samples in cups 3 through 12 of the sample cup rack.
6. Using the GEMSTAR pipettor with 10ul pipettes, aspirate samples into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.
7. Check that the GEMSTAR temperature light is on.
8. Enter CHEMISTRY 13, C13 will appear on the display.
9. Enter the standard concentration by pressing the STD key.
10. Press the CONTINUE key, FINI will appear on the display.
11. Enter CHEMISTRY 13, C13 will appear on the display.
12. Press the RUN key. ID will appear on the display.
13. Enter the RUN identification number. Press CONTINUE.
14. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.
15. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

16. In approximately 3 minutes, the Glucose assay will be completed and the results printed in mg/dl.

EXPECTED VALUES:
Serum/Plasma: 65 – 110

When Glucose values exceed 400 mg/dl, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

QC Factor Limits: 250 - 310

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Glucose Ox.
Catalog : G7519

REAGENT PREPARATION: Reconstitute each vial according to package insert instructions.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear sides aligned front and back.
2. Place the cuvette carrier on its stand.
3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.
4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.
5. Place distilled water in cup 1, Glucose standard or calibrator in cup 2, and samples in cups 3 through 12 of the sample cup rack.
6. Using the GEMSTAR pipettor with 10ul pipettes, aspirate samples into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.
7. Check that the GEMSTAR temperature light is on.
8. An open channel must be used for Glucose Oxidase: example No. 34.
9. Press CONTINUE and enter the following parameters:

1. TC	1
2. TEMP (°C)	37
3. UNITS (mg/dl)	3
4. DEC. PT.	0
5. # OF READS	1
6. INC. 1 (SEC)	240
7. INC. 2 (SEC)	60
8. DIR	1
9. FW POS 1	6
10. FW POS 2	0
11. FIRST READ (SEC)	60
12. DELTA T (SEC)	0
13. REF READ	0.00
14. SEC. SIZE	0.00
15. SEOE X 1000	0.00
16. AUX. LIM.	2.000
17. FACTOR	0.0
18. MAX. DELTA ABS	0.0
19. MIN. RGT. ABS.	0.0
20. MAX. PRT.	400

10. Enter the standard concentration by pressing the STD key.
11. Press the CONTINUE key, FINI will appear on the display.
12. Enter CHEMISTRY number, press RUN. ID will appear on the display.
13. Enter the RUN identification number. Press CONTINUE.
14. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.
15. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

16. In approximately 10 minutes, the Glucose Oxidase assay will be completed and the results printed in mg/dl.

EXPECTED VALUES:
70 – 105 mg/dl

When Glucose values exceed 400 mg/dl, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

Rev. 03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: HDL Cholesterol
Catalog : H7507,H7511

REAGENT PREPARATION: Reconstitute each vial according to package insert instructions.

SAMPLE PREPARATION: In order to assay for HDL Cholesterol, the LDL and VLDL fractions are precipitated out of the sample according to the procedure detailed in the package insert.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear side aligned front and back.
2. Place the cuvette carrier on its stand.
3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.
4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.
5. Place distilled water in cup 1, a cholesterol standard or calibrator in cup 2, and samples in cups 3 through 12 of the sample cup rack.
6. Using the GEMSTAR pipettor with 50ul pipettes, aspirate sample into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.
7. Check that the GEMSTAR temperature light is on.
8. Enter CHEMISTRY 10, C10 will appear on the display.
9. Enter the standard concentration by pressing the STD key.
10. Press the CONTINUE key, FINI will appear on the display.
11. Enter CHEMISTRY 10, C10 will appear on the display.
12. Press the RUN key. ID will appear on the display.
13. Enter the RUN identification number. Press CONTINUE.
14. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.
15. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

16. In approximately 10 minutes, the HDL Cholesterol assay will be completed and the results printed.

EXPECTED VALUES:
30 – 75 mg/dl

When the total cholesterol values exceed 600 mg/dl, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Hemoglobin
Catalog : H7504

REAGENT PREPARATION: Reagent comes ready to use.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear side aligned front and back.
2. Place the cuvette carrier on its stand.
3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.
4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.
5. Check that the GEMSTAR temperature light is on.
6. Enter CHEMISTRY 18, C18 will appear on the display.
7. Press the RUN key. ID will appear on the display.
8. Enter the RUN identification number. Press CONTINUE.
9. Place distilled water in cup 1, and controls and samples in cups 2 through 12 of the sample cup rack.
10. Using the GEMSTAR pipettor with 10ul pipettes, aspirate sample into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.
11. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.
12. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

13. In approximately 3 minutes, the Hemoglobin assay will be completed and the results printed.

EXPECTED VALUES:
Males 13 – 19 g/dL
Females 11 – 16 g/dL

When Hemoglobin values exceed 20 g/dL, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

NOTE: USE ONLY WELL MIXED BLOOD SAMPLES. DO NOT ALLOW SAMPLES TO REMAIN IN SAMPLE CUPS LONGER THAN ONE MINUTE PRIOR TO ASPIRATION.

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Calcium (Ars)
Cataog: C7529

(FOR GEMSTAR II ONLY)

REAGENT PREPARATION: Ready to use liquid.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear sides aligned front and back.

2. Place the cuvette carrier on its stand.

3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.

4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.

5. Place distilled water in cup 1, Calcium standard or calibrator in cup 2, and samples in cups 3 through 12 of the sample cup rack.

6. Using the GEMSTAR pipettor with 10ul pipettes, aspirate samples into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.

7. Check that the GEMSTAR temperature light is on.

8. An open channel must be used for Calcium, for example: No. 35.

9. Press continue and enter the following parameters:

1. TC	1
2. TEMP (^{o}C)	37
3. UNITS (mg/dl)	3
4. DEC. PT.	1
5. # OF READS	1
6. INC. 1 (SEC)	60
7. INC. 2 (SEC)	60
8. DIR	1
9. FW POS 1	15
10. FW POS 2	0
11. FIRST READ (SEC)	300
12. DELTA T (SEC)	0
13. REF READ	0.000
14. SEC. SIZE	0.000
15. SEOE X 1000	0.000
16. AUX. LIM.	2.000
17. FACTOR	0.0
18. MAX. DELTA ABS	0.000
19. MIN. RGT. ABS.	0.750
20. MAX. PRT	1.50
21. DRB FAC	0.986

10. Enter the standard concentration by pressing the STD key.

11. Press the CONTINUE key, FINI will appear on the display.

12. Enter CHEMISTRY #, Press RUN.

13. Enter the RUN identification number. Press CONTINUE.

14. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.

15. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

16. In approximately 10 minutes, the Calcium assay will be completed and the results printed.

EXPECTED VALUES:
8.5 – 10.4 mg/dl

When Calcium values exceed 15.0 mg/dl, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

QC Factor Limits: 9 - 15

Rev. 6/01

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Calcium (Dry)
Cataog: C7508

(FOR GEMSTAR II ONLY)

REAGENT PREPARATION: Reconstitute each vial according to package insert instructions.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear sides aligned front and back.
2. Place the cuvette carrier on its stand.
3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.
4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.
5. Place distilled water in cup 1, Calcium standard or calibrator in cup 2, and samples in cups 3 through 12 of the sample cup rack.
6. Using the GEMSTAR pipettor with 10ul pipettes, aspirate samples into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.
7. Check that the GEMSTAR temperature light is on.
8. An open channel must be used for Calcium, for example: No. 35.
9. Press continue and enter the following parameters:

1. TC	1
2. TEMP (°C)	37
3. UNITS (mg/dl)	3
4. DEC. PT.	1
5. # OF READS	1
6. INC. 1 (SEC)	60
7. INC. 2 (SEC)	60
8. DIR	1
9. FW POS 1	14
10. FW POS 2	0
11. FIRST READ (SEC)	60
12. DELTA T (SEC)	0
13. REF READ	0.000
14. SEC. SIZE	0.000
15. SEOE X 1000	0.00
16. AUX. LIM.	2.000
17. FACTOR	0.000
18. MAX. DELTA ABS	0.000
19. MIN. RGT. ABS.	0.600
20. MAX. PRT.	15.0
21. DRB FAC	0.986

10. Enter the standard concentration by pressing the STD key.
11. Press the CONTINUE key, FINI will appear on the display.
12. Enter CHEMISTRY #, Press RUN.
13. Enter the RUN identification number. Press CONTINUE.
14. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.
15. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

16. In approximately 10 minutes, the Calcium assay will be completed and the results printed.

EXPECTED VALUES:
8.5 – 10.4 mg/dl
When Calcium values exceed 15.0 mg/dl, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

QC Factor Limits: 19 - 34
Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Phosphorus UV
Cataog: P7516

REAGENT PREPARATION: Reagent comes ready to use.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear side aligned front and back.
2. Place the cuvette carrier on its stand.
3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.
4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.
5. Place distilled water in cup 1, Phosphorus calibrator, a serum based calibrator, must be used in this procedure, in cup 2, and sample in cups 3 through 12 of the sample cup rack.
6. Using the GEMSTAR pipettor with 10ul pipettes, aspirate sample into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.
7. Check that the GEMSTAR termperature light is on.
8. Enter CHEMISTRY 14, C14 will appear in the display.
9. Enter the standard concentration by pressing the STD key.
10. Press the CONTINUE key, FINI will appear on the display.
11. Enter CHEMISTRY 14, C14 will appear on the display.
12. Press the RUN key. ID will appear on the display.
13. Enter the RUN identification number. Press CONTINUE.
14. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.
15. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

16. In approximately 3 minutes, the Phosphorus assay will be completed and the results printed.

EXPECTED VALUES:
2.5 – 4.8 mg/dl

When Phosphorus values exceed 10.0 mg/dl, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

QC Factor Limits: 20 - 30

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: LDH-L
Catalog: L7535

REAGENT PREPARATION: Reconstitute each vial according to package insert instructions.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear sides aligned front and back.
2. Place the cuvette carrier on its stand.
3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.
4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.
5. Check that the GEMSTAR temperature light is on.
6. Enter CHEMISTRY 4, C4 will appear on the display.
7. Press the RUN key. ID will appear on the display.
8. Enter the RUN identification number. Press CONTINUE.
9. Place distilled water in cup 1, and controls and samples in cups 2 through 12 of the sample cup rack.
10. Using the GEMSTAR pipettor with 10ul pipettes, aspirate samples into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.
11. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.
12. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

13. In approximately 3 minutes, the LDH-L assay will be completed and the results printed in U/L at 37°C.

EXPECTED VALUES:
Males: 80 – 285 U/L (37°C)
Females: 103 – 227 U/L (37°C)

When LD values exceed 700 U/L, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

Reagent Drift Limits: -25 to +15

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Lipase (colorimetric)
Catalog: L7503

REAGENT PREPARATION: Reconstitute each vial according to package insert instructions.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear side aligned front and back.

2. Place the cuvette carrier on its stand.

3. Using a 25ul pipette, place distilled water in cuvette 1, Lipase standard in cuvette 2 and controls and samples into the subsequent cuvettes.

4. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.

5. Place the cover tape on the cuvettes, mix using the cuvette carrier, and place the cuvettes into the GEMSTAR.

6. Check that the GEMSTAR temperature light is on.

7. An open channel must be used for Lipase, for example No. 36.

8. Press CONTINUE and enter the following parameters:

1. TC		4
2. TEMP (°C)	37	
3. UNITS (mg/dl)		2
4. DEC. PT.		0
5. # OF READS		3
6. INC. 1 (SEC)		300
7. INC. 2 (SEC)		60
8. DIR		1
9. FW POS 1	8	
10. FW POS 2		0
11. FIRST READ (SEC)	180	
12. DELTA T (SEC)		60
13. REF READ		0.000
14. SEC. SIZE		1.000
15. SEOE x 1000		1.000
16. AUX. LIM.	1.000	
17. FACTOR	0.0	
18. MAX. DELTA ABS.	0.000	
19. MIN. RGT. ABS.		0.000
20. MAX. PRT.		500

9. Enter the standard concentration by pressing the STD key.

10. Press the CONTINUE key, FINI will appear on the display.

11. Enter CHEMISTRY number, press RUN, ID will appear on the display.

12. Enter the RUN identification number. Press CONTINUE.

13. Place Lipase activator into the sample cups and using the Gemstar 50ul pipettes, aspirate activator into the pipette tips as described in section 3.5.4.3 of the GEMSTAR operating manual.

14. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.

15. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

16. In approximately 6 minutes, the Lipase assay will be completed and the results printed.

EXPECTED VALUES:
0 – 62 U/L

When Lipase values exceed 500 U/L, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

QC Factor Limits: 3000 – 480
Rev.6/01

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Magnesium
Catalog: M7527

REAGENT PREPARATION: Combine 10 volumes of Color with 1 volume of Buffer in a disposable plastic container. Mix.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear side aligned front and back.

2. Place the cuvette carrier on its stand.

3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.

4. Place the cover tape on the cuvettesand place the cuvettes into the GEMSTAR.

5. Place distilled water in cup 1, Magnesium standard or calibrator in cup 2, and samples in cups 3 through 12 of the sample cup rack.

6. Using the GEMSTAR pipettor with 10ul pipettes, aspirate samples into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.

7. Check that the GEMSTAR temperature light is on.

8. An open channel must be used for Magnesium: example No. 35.

9. Press CONTINUE and enter the following parameters:

1. TC		1
2. TEMP (°C)	37	
3. UNITS (mg/dl)		5
4. DEC. PT.		1
5. # OF READS		1
6. INC. 1 (SEC)		60
7. INC. 2 (SEC)		60
8. DIR		1
9. FW POS 1	6	
10. FW POS 2		0
11. FIRST READ (SEC)	60	
12. DELTA T (SEC)		0
13. REF READ		0.000
14. SEC. SIZE		0.000
15. SEOE x 1000		0.000
16. AUX. LIM.	2.000	
17. FACTOR	0.0	
18. MAX. DELTA ABS.	0.000	
19. MIN. RGT. ABS.		0.000
20. MAX. PRT.		4.0

10. Enter the standard concentration by pressing the STD key.

11. Press the CONTINUE key, FINI will appear on the display.

12. Enter CHEMISTRY number, press RUN. ID will appear on the display.

13. Enter the RUN identification number. Press CONTINUE.

14. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.

15. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

16. In approximately 3 minutes, the Magnesium assay will be completed and the results printed in mEq/L.

EXPECTED VALUES:

Newborns: 1.5 – 2.3 mEq/L
Children: 1.4 – 1.9 mEq/L
Adults: 1.3 – 2.5 mEq/L

When Magnesium values exceed 4.0 mEq/L, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

QC Factor Limits: 10 - 15

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Potassium
Catalog: P7520

REAGENT PREPARATION: Prepare reagent according to package insert instructions.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear side aligned front and back.

2. Place the cuvette carrier on its stand.

3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.

4. Place the cover tape on the cuvettesand place the cuvettes into the GEMSTAR.

5. Place distilled water in cup 1, Potassium calibrator in cup 2, and samples in cups 3 through 12 of the sample cup rack.

6. Using the GEMSTAR pipettor with 10ul pipettes, aspirate samples into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.

7. Check that the GEMSTAR temperature light is on.

8. An open channel must be used for Potassium: example No. 39.

9. Press CONTINUE and enter the following parameters:

1. TC		1
2. TEMP (°C)	37	
3. UNITS (mg/dl)		1
4. DEC. PT.		1
5. # OF READS		3
6. INC. 1 (SEC)		60
7. INC. 2 (SEC)		60
8. DIR		1
9. FW POS 1	15	
10. FW POS 2		0
11. FIRST READ (SEC)	180	
12. DELTA T (SEC)		0
13. REF READ		0.000
14. SEC. SIZE		0.000
15. SEOE x 1000		0.000
16. AUX. LIM.	2.000	
17. FACTOR	0.0	
18. MAX. DELTA ABS.	0.000	
19. MIN. RGT. ABS.		0.000
20. MAX. PRT.		8.0

10. Enter the standard concentration by pressing the STD key.

11. Press the CONTINUE key, FINI will appear on the display.

12. Enter CHEMISTRY number, press RUN. ID will appear on the display.

13. Enter the RUN identification number. Press CONTINUE.

14. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.

15. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

16. In approximately 5 minutes, the Potassium assay will be completed and the results printed.

EXPECTED VALUES:
3.4 – 5.3 mEq/L

When Potassium values exceed 8.0 mEq/L, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

Rev. 6/01

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Total Bilirubin
Catalog: B7576

REAGENT PREPARATION: Prepare working reagent by adding 100ul (.10ml) of Nitrite Reagent per 10ml of Total Bilirubin Reagent.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear sides aligned front and back.
2. Place the cuvette carrier on its stand.
3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.
4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.
5. Place distilled water in cup 1, Total Bilirubin calibrator in cup 2, and samples in cups 3 through 12 of the sample cup rack.
6. Using the GEMSTAR pipettor with 50ul pipettes, aspirate samples into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.
7. Check that the GEMSTAR temperature light is on.
8. Enter CHEMISTRY 16, C16 will appear on the display.
9. Enter the standard concentration by pressing the STD key.
10. Press the CONTINUE key, FINI will appear on the display.
11. Enter CHEMISTRY 16, C16 will appear on the display.
12. Press the RUN key. ID will appear on the display.
13. Enter the RUN identification number. Press CONTINUE.
14. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.
15. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

16. In approximately 7 minutes, the Total Bilirubin assay will be completed and the results printed.

EXPECTED VALUES:
0.2 – 1.2 mg/dl

When Total Bilirubin values exceed 20.0 mg/dl, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

QC Factor Limits: 12 - 19

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Total Iron/TIBC
Catalog: I7504,I7506

REAGENT PREPARATION: All reagents are ready to use.

ADDITIONAL MATERIALS REQUIRED:
Pipettes capable of delivering 15uL and 100uL are required for this assay.

OPEN CHANNEL PROGRAMMING:
Two open channels are required: one for blank run and one for test run.

Refer to section 3.11.1 of the GEMSTAR operating manual for directions regarding programming an open channel.

PARAMETERS – BLANK RUN

1. TC		1
2. TEMP (°C)	37	
3. UNITS (mg/dl)		4
5. # OF READS		0
4. DEC. PT.		1
6. INC. 1 (SEC)		60
7. INC. 2 (SEC)		60
8. DIR		1
9. FW POS 1	14	
10. FW POS 2		0
11. FIRST READ (SEC)	180	
12. DELTA T (SEC)		0
13. REF READ		0.000
14. SEC. SIZE		0.000
15. SEOE x 1000		0.0
16. AUX. LIM.	2.000	
17. FACTOR	0.0	
18. MAX. DELTA ABS.	0.000	
19. MIN. RGT. ABS.		0.000
20. MAX. PRT.		500

PARAMETERS – TEST RUN

1. TC		1
2. TEMP (°C)	37	
3. UNITS (mg/dl)		4
5. # OF READS		0
4. DEC. PT.		1
6. INC. 1 (SEC)		60
7. INC. 2 (SEC)		60
8. DIR		1
9. FW POS 1	14	
10. FW POS 2		0
11. FIRST READ (SEC)	600	
12. DELTA T (SEC)		0
13. REF READ		0.000
14. SEC. SIZE		0.000
15. SEOE x 1000		0.0
16. AUX. LIM.	2.000	
17. FACTOR	0.0	
18. MAX. DELTA ABS.	0.000	
19. MIN. RGT. ABS.		0.000
20. MAX. PRT.		500

PROCEDURE: (IRON BLANK RUN)

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear side aligned front and back.

2. Place the cuvette carrier on its stand.

3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.

4. Manually pipette 100uL distilled water to cuvette 1. Add 100uL standard to cuvette 2 and 100uL control and sample in cuvettes 3 through 12.

5. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.

6. Check that the GEMSTAR temperature light is on.

7. Enter the open channel chemistry number for the Iron Blank run by pressing CHEMISTRY and the open channel number chosen. The number programmed will appear on the display.

8. Enter the standard concentration by pressing the STD key. The display will show the last standard concentration that was entered for that open channel. If this value is no longer applicable, enter the correct standard value. The 500 ug/dL standard contained in the kit is used and is entered as 500 CONTINUE.

9. To begin the Iron Blank run, press the CHEMISTRY key and enter the chemistry number programmed for the Iron Blank assay. C# CHOSEN will appear on the display.

10. Press the RUN key. ID will appear on the display.

11. Enter the RUN identification number. Press CONTINUE.

12. When alerted by the audible signal at the end of the incubation, open the door and dispense 15uL of Iron Color Reagetn into cuvette 2 only.

13. Close the door and immediately press the RUN key.

14. In approximately 3 minutes, the Iron Blank Assay will be completed and the results printed.

15. Do not remove cuvettes from the GEMSTAR. Immediately proceed to Iron Test Run.

PROCEDURE: (IRON TEST RUN)

1. To begin the Iron Test run, enter the open channel chemistry number for the Iron Test Assay by pressing CHEMISTRY and the open channel number chosen. The number programmed will appear on the display.

2. Enter the standard concentration by pressing the STD key. The display will show the last standard concentration that was entered for that open channel. If this value is no longer applicable, enter the correct standard value. The 500ug/dL standard contained in the kit is used and is entered as 500 CONTINUE.

3. To begin the Iron Test run, press the CHEMISTRY key and enter the chemistry number programmed for the Iron Test assay. C# CHOSEN will appear on the display.

4. Press the RUN key, ID will appear on the display.

5. Enter the RUN identification number. Press CONTINUE.

6. When alerted by the audible signal at the end of the incubation, open the door and dispense 15uL of Iron Color Reagent into cuvette 1, and cuvettes 3 through 12.

7. Close the door and immediately press the RUN key.

8. In approximately 10 minutes, the Iron Test Assay will be completed and the results printed.

NOTE: DISREGARD TIMING ERRORS SINCE THE LOAD TIME WILL HAVE BEEN EXCEEDED.

CALCULATION OF SERUM IRON:

In order to obtain Serum Iron values corrected for the serum blank, subtract value obtained on the blank run from the value obtained on the test run for each sample.

EXCESS IRON:

The same open channel parameters previously used for Iron are also used for Excess Iron. No additional open channel programming is required. Use the Iron Blank and Iron Test open channel number previously programmed to determine Excess Iron values. To assay Excess Iron on GEMSTAR, perform a blank and a test run. Use the same cuvettes for both runs.

EXPECTED VALUES:

Serum Iron: 60 – 150 ug/dL
Serum TIBC: 250 – 400 ug/dL

REAGENT AND SAMPLE DISPENSING:

1. Holding the cuvettes at the very top, wipe each with a lint-free tissue. Place the necessary number of cuvettes into the cuvette stand with the clear sides aligned front and back. Cuvettes 1 and 2 are used for the reagent blank and standard respectively, allowing up to 10 control or unknown samples to be assayed in a single batch run.

2. Place the cuvette carrier on its stand.

3. Set the SELECTAPETTE to .6(mL) and dispense 0.6mL UIBC Buffer Reagent into each cuvette.

4. Manually add 100uL Iron Standard to cuvettes 2 through 12. Add 200uL water to cuvette 1 and 100uL water to cuvette 2. Next manually add 100uL controls and samples to cuvettes 3 through 12.

5. Place the cover tape on the cuvettes.

6. Using the carrier, place the cuvettes into the GEMSTAR. Be sure that the cuvettes are properly seated in the shuttle.

7. Close the door.

ASSAY PROCEDURE FOR EXCESS IRON:

The assay for the Excess Iron is performed exactly as the Serum Iron. Follow the same steps of the assay procedure as previously described using the same blank and test channel.

NOTE: DISREGARD TIMING ERRORS SINCE THE LOAD TIME WILL HAVE BEEN EXCEEDED.

CALCULATION OF EXCESS IRON:
Subtract the value obtained from the Excess Iron Test Run minus the Excess Iron Blank Run to obtain the Excess Iron.

CALCULATION OF UNSATURATED IRON-BINDING CAPACITY (UIBC)
The Unsaturated Iron-Binding Capacity is calculated by subtracting the Total Iron added (500ug/dL) minus the Excess Iron obtained. UIBC (ug/dL) = Total Iron Added (500ug/dL) – Excess Iron (ug/dL).

CALCULATION OF TOTAL IRON-BINDING CAPACITY (TIBC):
The Total Iron-Binding Capacity is calculated by adding the Serum Iron and Unsaturated Iron Binding Capacity (UIBC) values. TIBC (ug/dL)=Serum Iron(ug/dL)+UIBC(ug/dL).

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Total Protein
Catalog: P7528

REAGENT PREPARATION: Reagent is ready to use.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear side aligned front and back.
2. Place the cuvette carrier on its stand.
3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.
4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.
5. Place distilled water in cup 1, Total protein, standard or calibrator in cup 2, and samples in cups 3 through 12 of the sample cup rack.
6. Using the GEMSTAR pipettor with 10ul pipettes, aspirate samples into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.
7. Check that the GEMSTAR temperature light is on.
8. Enter CHEMISTRY 17, C17 will appear on the display.
9. Enter the standard concentration by pressing the STD key.
10. Press the CONTINUE key, FINI will appear on the display.
11. Enter CHEMISTRY 17, C17 will appear on the display.
12. Press the RUN key. ID will appear on the display.
13. Enter the RUN identification number. Press CONTINUE.
14. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.
15. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

16. In approximately 4 minutes, the Total Protein assay will be completed and the results printed.

EXPECTED VALUES:
6.2 – 8.5 g/dl

When Total Protein values exceed 10.0 g/dl, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

QC Factor Limits: 20 - 30

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Triglyceride (GPO)
Catalog: T7531

REAGENT PREPARATION: Reconstitute each vial according to package insert instructions.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear side aligned front and back.

2. Place the cuvette carrier on its stand.

3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.

4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.

5. Place distilled water in cup 1, Triglyceride standard or calibrator in cup 2, and samples in cups 3 through 12 of the sample cup rack.

6. Using the GEMSTAR pipettor with 10ul pipettes, aspirate sample into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.

7. Check that the GEMSTAR temperature light is on.

8. An open channel must be used for Trig-GPO: example No. 36.

9. Press CONTINUE and enter the following parameters:

1. TC	1
2. TEMP (^{o}C)	37
3. UNITS (mg/dl)	3
4. DEC. PT.	0
5. # OF READS	1
6. INC. 1 (SEC)	240
7. INC. 2 (SEC)	60
8. DIR	1
9. FW POS 1	8
10. FW POS 2	0
11. FIRST READ (SEC)	300
12. DELTA T (SEC)	0
13. REF READ	0.000
14. SEC. SIZE	0.000
15. SEOE x 1000	0.000
16. AUX. LIM.	2.000
17. FACTOR	0.0
18. MAX. DELTA ABS.	0.000
19. MIN. RGT. ABS.	0.000
20. MAX. PRT.	700

10. Enter the standard concentration by pressing the STD key.

11. Press the CONTINUE key, FINI will appear on the display.

12. Enter CHEMISTRY number, press RUN. ID will appear on the display.

13. Enter the RUN identification number. Press CONTINUE.

14. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.

15. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

16. In approximately 5 minutes, the Trig-GPO assay will be completed and the results printed in mg/dl.

EXPECTED VALUES:
36 – 165 mg/dl

When Triglyceride values exceed 700 mg/dl, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

Rev. 1-03

Pointe Scientific, Inc.

Instrument Application

Analyzer: Gemstar
Test: Uric Acid
Catalog: U7580

REAGENT PREPARATION: Reconstitute each vial according to package insert instructions.

PROCEDURE:

1. Place the necessary number of clean cuvettes into the cuvette stand with the clear sides aligned front and back.
2. Place the cuvette carrier on its stand.
3. Set the SELECTAPETTE to 0.7 (ml) and dispense 0.7ml of the reagent into each cuvette.
4. Place the cover tape on the cuvettes and place the cuvettes into the GEMSTAR.
5. Place distilled water in cup 1, Uric Acid standard or calibrator in cup 2, and samples in cups 3 through 12 of the sample cup rack.
6. Using the GEMSTAR pipettor with 50ul pipettes, aspirate samples into the pipette tips as described in section 3.5.4.3. of the GEMSTAR operating manual.
7. Check that the GEMSTAR temperature light is on.
8. Enter CHEMISTRY 11, C11 will appear on the display.
9. Enter the standard concentration by pressing the STD key.
10. Press the CONTINUE key, FINI will appear on the display.
11. Enter CHEMISTRY 11, C11 will appear on the display.
12. Press the RUN key. ID will appear on the display.
13. Enter the RUN identification number. Press CONTINUE.
14. When alerted by the audible signal at the end of the incubation, open the door and dispense samples using previously loaded pipettor as instructed in Section 3.5.4.4. of the GEMSTAR operating manual.
15. Quickly remove the pipettor and close the door. Immediately press the RUN key.

NOTE: THE RUN KEY MUST BE DEPRESSED WITHIN 15 SECONDS OF OPENING THE DOOR OR THE RESULTS MAY BE QUESTIONABLE.

16. In approximately 9 minutes, the Uric Acid assay will be completed and the results printed in mg/dl.

EXPECTED VALUES:
2.5 – 7.7 mg/dl

When Uric Acid values exceed 13.0 mg/dl, dilute sample with an equal volume of saline. Repeat assay and multiply result by 2.

QC Factor Limits: 8 - 16

Rev. 1-03