【Product Name】

Health Check Plus Profile (15+5)

【Packing Specification】

Type B: 1 Test / Disc,10Discs/Box.
Type B with diluent container.

【Testing Instrument】

CelercareV or PointcareV chemistry analyzer

【Intended Use】

Health Check Plus Profile (15+5) used with the CelercareV or the PointcareV chemistry analyzer, is intended to be used for the in vitro quantitative determination of total Protein (TP), albumin (ALB), alanine aminotransferase (ALT), alkaline phosphatase (ALP), total bilirubin (TBIL),creatinine (CRE), urea nitrogen (BUN), glucose (GLU), total cholesterol (CHOL),amylase (AMY), calcium (Ca), phosphorus (P), total bile acids (TBA), potassium (K^+), sodium (Na^+) in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.
The Health Check Plus Profile (15+5) measurements are used in the diagnosis of liver and gallbladder diseases, urinary system diseases, glucose metabolism and lipid metabolism disorders, pancreatic diseases, cardiovascular diseases.

【Principles of Testing】

The Health Check Plus Profile (15+5) is used to quantitatively test the concentration of the 15 biochemical indicators in the sample, which is based on the spectrophotometry. The principles are as follows:

1. Total Protein (TP)

The total protein method is a Biuret reaction, the protein solution is treated with cupric [Cu(II)] ions in a strong alkaline medium. The Cu(II) ions react with peptide bonds between the carbonyl oxygen and amide nitrogen atoms to form a colored Cu-protein complex.
The amount of total protein present in the sample is directly proportional to the absorbance of the Cu-protein complex. The total protein test is an endpoint reaction and the absorbance is measured as the difference in absorbance between 546 nm and 800 nm.

$$\text{Total Protein} + \text{Cu(II)} \xrightarrow{OH^-} \text{Cu-Protein Complex}$$

2. Albumin (ALB)

Bromcresol green (BCG), when bound with albumin, changes color from a yellow to green color. The absorbance maximum changes with the color shift.

$$\text{BCG} + \text{Albumin} \xrightarrow{\text{Acid pH}} \text{Albumin Complex}$$

Bound albumin is proportional to the concentration of albumin in the sample. This is an endpoint reaction that is measured as the difference in absorbance between 600 nm and 700 nm.

3. Alanine Aminotransferase (ALT)

ALT catalyzes the transfer of an amino group from L-alanine toα-ketoglutarate to form L-glutamate and

pyruvate. Lactate dehydrogenase catalyzes the conversion of pyruvate to lactate. Concomitantly, NADH is oxidized to NAD^+, as illustrated in the following reaction scheme.

$$\text{L-Alanine} + \alpha\text{-Ketoglutarate} \xrightarrow{ALT} \text{L-Glutamate} + \text{Pyruvate}$$

$$\text{Pyruvate} + \text{NADH} + H^+ \xrightarrow{LDH} \text{Lactate} + NAD^+$$

The rate of change of the absorbance difference between 340 nm and 405 nm is due to the conversion of NADH to NAD^+ and is directly proportional to the amount of ALT present in the sample.

4. Alkaline Phosphatase (ALP)

Under the catalysis of ALP, the Phosphoric acid on nitrobenzene (4-NNP) was turned into Para nitro phenol (4-NP).4-NP shows a yellow color in alkaline solution. At the wavelength of 405/505nm, the ALP activity can be calculated by monitoring the absorbance change rate.

$$\text{4-NNP} \xrightarrow{ALP} \text{Acyl phosphate} + \text{4-NP}$$

5. Total Bilirubin (TBIL)

In the enzyme procedure, bilirubin is oxidized by bilirubin oxidase (BOD) into biliverdin. Bilirubin is quantitated as the difference in absorbance between 450nm and 546 nm. The initial absorbance of this endpoint reaction is determined from the bilirubin blank cuvette and the final absorbance is obtained from the bilirubin test cuvette. The amount of bilirubin in the sample is proportional to the difference between the initial and final absorbance measurements.

$$\text{Bilirubin} + O_2 \xrightarrow{BOD} \text{Biliverdin} + H_2O$$

6. Creatinine (CRE)

In the coupled enzyme reactions, creatinineamidohydrolase (CAH) hydrolyzes creatinine to creatine. A second enzyme, creatineamidinohydrolase (CRH), catalyzes the formation of sarcosine from creatine. Sarcosine oxidase (SAO) causes the oxidation of sarcosine to glycine, formaldehyde and hydrogen peroxide (H_2O_2). In a Trinder finish, peroxidase (POD) catalyzes the reaction among the hydrogen peroxide, 2,4,6-tribromo-3-hydroxybenzoic acid (TBHBA)and 4-aminoantipyrine (4-AAP) into a red quinoneimine dye. Potassium ferrocyanide and ascorbate oxidase are added to the reaction mixture to minimize the potential interference of bilirubin and ascorbic acidrespectively.

$$\text{Creatinine} + H_2O \xrightarrow{CAH} \text{Creatine}$$

$$\text{Creatine} + H_2O \xrightarrow{CRH} \text{Sarcosine} + \text{Urea}$$

$$\text{Sarcosine} + H_2O + O_2 \xrightarrow{SAO} \text{Glycine} + \text{Formaldehyde} + H_2O_2$$

$$H_2O_2 + \text{TBHBA} + \text{4-AAP} \xrightarrow{POD} \text{Red Quinoneimine Dye} + H_2O$$

Two cuvettes are used to determine the concentration of creatinine in the sample. Endogenous creatine is measured in the blank cuvette, which is subtracted from the combined endogenous creatine and the creatine formed from the enzyme reactions in the test cuvette. Once the endogenous creatine is eliminated from the calculations, the concentration of creatinine is proportional to the intensity of the red color produced. The endpoint reaction is measured as the difference in absorbance at 546 nm and 700 nm.

7. Urea Nitrogen（BUN）

In the coupled-enzyme reaction, urease hydrolyzes urea into ammonia and carbon dioxide. Upon combining ammonia withα-oxoglutarate and reduced nicotinamide adenine dinucleotide (NADH), the

enzyme glutamate dehydrogenase (GLDH) oxidizes NADH to NAD^+.

$$Urea + 2H_2O \xrightarrow{Urease} 2NH_4^+ + CO_3^{2-}$$

$$NH_4^+ + \alpha\text{-Oxoglutarate} + NADH \xrightarrow{GLDH} L\text{-Glutamate} + H_2O + NAD^+$$

The rate of change of the absorbance difference between 340 nm and 405 nm is caused by the conversion of NADH to NAD^+ and is directly proportional to the amount of urea present in the sample.

8. Glucose (GLU)

The reaction of glucose with adenosine triphosphate (ATP)catalyzed by hexokinase (HK), produces glucose-6-phosphate (G-6-P) and adenosine diphosphate (ADP). Glucose-6-phosphate dehydrogenase (G-6-PDH) catalyzes the reaction of G-6-P into 6-phosphogluconate and the reduction of nicotinamide adenine dinucleotide phosphate ($NADP^+$) to NADPH.

$$Glucose + ATP \xrightarrow{HK} Glucose\text{-}6\text{-}Phosphate + ADP$$

$$G\text{-}6\text{-}P + NADP^+ \xrightarrow{G\text{-}6\text{-}PDH} 6\text{-}Phosphogluconate + NADPH + H^+$$

The absorbance is measured bichromatically at 340 nm and 405 nm. The production of NADPH is directly proportional to the amount of glucose present in the sample.

9. Total Cholesterol (CHOL)

The reaction of CHOL is an enzymatic end-point method that uses cholesterol esterase (CE) and cholesterol dehydrogenase (CHDH). CE hydrolyzes cholesterol esters to form cholesterol and fatty acids. The CHDH reaction converts cholesterol to cholest-4-en-3-one. The NADH is measured bichromatically at 340 nm and 405 nm. NADH production is directly proportional to theamount of cholesterol present. An assay-specific blank is also monitored to ensure no extraneous reactions interfere with thecalculations of CHOL levels.

$$Cholesterol\ Esters + H_2O \xrightarrow{CE} Cholesterol + Fatty\ Acids$$

$$Cholesterol + NAD^+ \xrightarrow{CHDH} Cholest\text{-}4\text{-}en\text{-}3\text{-}one + NADH + H^+$$

10. Amylase (AMY)

In the coupled-enzyme reaction, amylase in the sample hydrolyzes 2-chloro-*p*-nitrophenyl-α-D-maltotrioside (CNP-G3) to 2-chloro-4-nitrophenol (CNP) producing color and D-maltotrioside. The change in absorbance of the CNP is directly proportional to the amylase activity in the sample at 405nm and 505 nm.

$$CNP\text{-}G3 \xrightarrow{AMY} CNP + G3$$

11. Calcium (Ca)

Calcium in the patient sample binds with arsenazo III to form a calcium-dye complex.

$$Ca^{2+} + Arsenazo\ III \longrightarrow Ca^{2+}\text{-}Arsenazo\ III\ Complex$$

It is an endpoint reaction. The amount of total calcium in the sample is proportional to the absorbance.

12. Phosphorus (P)

Theenzymatic method for the MNCHIP system uses maltose phosphorylase (MP) coupled through β-phosphoglucomutase (β-PGM) and glucose-6-phosphate dehydrogenase (G6PDH). The amount of NADH formed can be measured as anendpoint at 340/405 nm.

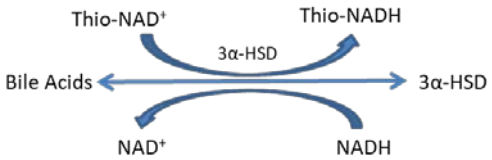
$$\text{Maltose} + \text{Pi} \xrightarrow{MP} \text{Glucose-1-Phosphate (G-1-P)} + \text{Glucose}$$

$$\text{Glucose-1-Phosphate (G-1-P)} \xrightarrow{\beta\text{-PGM}} \text{Glucose-6-Phosphate (G-6-P)}$$

$$\text{Glucose-6-Phosphate (G-6-P)} + NAD^+ \xrightarrow{\text{G6PDH}} NADH + \text{6-Phosphogluconate} + H^+$$

13. Total Bile Acids (TBA)

In the presence of the thio-derivative of nicotinamide adenine dinucleotide (Thio-NAD+) the enzyme 3-α-Hydroxysteroid Dehydrogenase (3-α-HSD) reversibly oxidizes bile acids to oxidized bile acids (3-α-keto forms) with the concomitant conversion of Thio-NAD+ to its reduced from Thio-NADH. In a cycling reaction, the oxidized bile acids are returned to their reduced state when excess NADH is present. The NADH is converted to NAD+. The rate of increase in absorbance at 405nm (Thio-NADH) is measured and is proportional to the concentration of bile acids in the sample. The rate is measured bichromatically at 405 and 500nm.



14. Potassium (K^+)

In the coupledenzyme reaction, pyruvate kinase (PK) dephosphorylates phosphoenolpyruvate (PEP) to form pyruvate. Lactate dehydrogenase (LDH) catalyzes conversion of pyruvate to lactate. Concomitantly, NADH is oxidized to NAD^+. The rate of change in absorbance due to the conversion of NADH to NAD^+ is directly proportional to the amount of potassium in the sample.
Interferences from other ions are minimized with the addition of some special ingredients.

$$\text{ADP} + \text{PEP} \xrightarrow{K^+,\ \text{PK}} \text{Pyruvate} + \text{ATP}$$

$$\text{Pyruvate} + NADH + H^+ \xrightarrow{LDH} \text{Lactate} + NAD^+$$

15. Sodium (Na^+)

In the enzymatic reaction, β-D-galactosidase is activated by the sodium in the sample. The activated enzymecatalyzes the reaction of o-nitrophenyl-β-D-galactopyranoside (ONPG) to o-nitrophenolandgalactose.

$$\text{ONPG} \xrightarrow{Na^+,\ \beta\text{-D-galactosidase}} \text{o-Nitrophenol} + \text{Galactose}$$

【Principle of Operation】

Refer to the CelercareV or the PointcareV chemistry analyzer Operator's Manual, for the Principles and Limitations of the Procedure.

【Description of Reagents】

Each Health Check Plus Profile (15+5) contains lyophilized test-specific reagent beads.A lyophilized blank reagent bead includes in each disc for a judgment of error 0233.
Type B is the reagent disc with diluent container.

Calibration information is included in barcode code. Please check it on the label.
The componen of each Health Check Plus Profile (15+5) is as follows(after redissolution):

Component	Quantity
Total protein assay reagent	13.5 μL
Albumin assay reagent	13.5 μL
Alanine Aminotransferase assay reagent	13.5 μL
Alkaline Phosphatase assay reagent	13.5 μL
Total Bilirubin assay reagent	13.5 μL
Creatinine assay reagent	13.5 μL
Urea assay reagent	13.5 μL
Glucose assay reagent	6.6 μL
Total Cholesterol assay reagent	13.5 μL
Potassium assay reagent	13.5 μL
Amylase assay reagent	13.5 μL
Calcium assay reagent	9.7μL
Phosphorus assay reagent	13.5 μL
Sodium assay reagent	13.5 μL
Total bile acids assay reagent	13.5μL
Stabilizer	Appropriate amount

【Storage】

Store reagent discs in their sealed pouches at a temperature of 2-8°C (36-46°F). Do not expose opened or unopened discs to direct sunlight or temperatures exceeding 32°C (90°F). Reagent discs may be used until the expiration date indicated on the package, which is also encoded in the unique code printed on the sealing pouch.
A torn or damaged pouch may allow moisture to reach the unused disc, adversely affecting its performance. Therefore, do not use any disc from a damaged pouch.

【Sample Requirements】

Sample collection techniques are described in the “Sample requirement” section of the CelercareV or the PointcareVchemistry analyzer Operator’s Manual.
The required sample usage is 100 μL of lithium heparin whole blood, lithium heparin plasma, serum or quality controls.
Whole blood samples collected by venipuncture must be homogeneous before transferring the sample to a reagent disc.

At the same time, it is necessary to carry out the test within 60 minutes. Before taking the test, shake the lithium heparin blood collection tube gently upside down several times.

The glucose concentration is affected by the patient's feeding time and the storage environment after the sample is collected. In order to accurately measure glucose, a sample of the patient should be taken after at least 12 hours of fasting. For uncentrifuged samples stored at room temperature, the glucose concentration is reduced by about 5-12 mg / dL in 1 hour.

Light may cause total bilirubin to decompose, causing deviations in the test results. Whole blood samples that are not tested immediately should be stored in a dark environment.

Use only lithium heparin evacuated specimen collection tubes for whole blood or plasma samples.

The test was started within 10 minutes after transferring the sample to the reagent disc.

【Interfering Substances】

Studies on known drugs or chemicals have found that when the interfering substances contained in the sample exceed the contents in the table below, the final test results are affected.

Analyte	Interfering substances concentration （≤）							
	Bilirubin mg/dL	Intralipid mg/dL	Hemoglobin mg/dL	Vitamin C mg/dL	Pyruvate mmol/L	Creatine μmol/L	NH_4Cl mmol/L	Mg^{2+} mmol/L
TP	25	1050	200	——	——	——	——	——
ALB	40	600	1000	——	——	——	——	——
ALT	40	600	50	50	1	——	——	——
ALP	40	1050	400	——	——	——	——	——
TBIL	——	1050	1000	75	——	——	——	——
CRE	40	1050	500	25	——	600	——	——
BUN	25	600	1000	——	——	——	1	——
GLU	40	600	1000	50	——	——	——	——
CHOL	40	1000	800	40	——	——	——	——
K^+	16	150	50	75	——	——	——	——
Na^+	10	150	50	75	——	——	——	——
AMY	40	1000	400	100	——	——	——	——
Ca	180	210	200	75	——	——	——	3
P	45	525	100	27	——	——	——	——
TBA	50	600	500	50	——	——	——	——

【Procedure】

■ **Materials Provided**

Health Check Plus Profile (15+5)

CelercareV or PointcareV chemistry analyzer

Please tear off the aluminum strip before using Type B.

Transfer pipettes (fixed volume 100 μL for sample) and tips

■ **Test Procedure**

The complete sample collection and step-by-step operating procedures are detailed in the Operator’s Manual for the Celercare V or Pointcare V chemistry analyzer.

■ **Calibration**

Each batch of reagent is calibrated using Randoxstandard serum to obtain the disc-specific calibration parameters before shipment.

The calibration parameters stored in the two-dimentional code printed on the sealed pouch are provided to analyzer at the time of scanning the code.

Refer to the Operator's Manual for specific information.

■ **Quality Control**

Refer to Operator's Manual of the CelercareV or the PointcareV chemistry analyzer. Performance of the CelercareVor the PointcareVchemistry analyzer can be verified by running controls. For a list of approved quality control materials with acceptance ranges, please consult the manual.

If control results are out of range, repeat one time. If still out of range, call MNCHIP customer service or local distributers for technical support. Do not report the results if controls are outside their labeled limits.

■ **Results**

The CelercareV or the PointcareV chemistry analyzer automatically calculates and prints the analyte concentrations in the sample. Details regarding endpoint and rate reaction calculations can be found in the Celercare V or the Pointcare V chemistry analyzer Operator's Manual.

【Normal Reference Ranges】

These ranges are provided as a guideline only. It is recommended that your office or institution establish normal ranges for your particular patient population.

Analyte	SI Units	Common Units
TP	Dog: 52 ~ 82g/L; Cat: 54 ~ 89g/L	Dog: 5.2 ~ 8.2g/dL; Cat: 5.4 ~ 8.9g/dL
ALB	Dog: 22 ~ 44g/L; Cat: 22 ~ 45g/L	Dog: 2.2 ~ 4.4 g/dL; Cat: 2.2 ~ 4.5 g/dL
ALT	Dog: 10 ~ 140U/L; Cat: 8.2 ~ 123U/L	Dog: 10 ~ 140U/L; Cat: 8.2 ~ 123U/L
ALP	Dog: 20 ~ 150U/L; Cat:10 ~ 90U/L	Dog: 20 ~ 150U/L; Cat:10 ~ 90U/L
TBIL	Dog: 2 ~ 15μmol/L; Cat: 2 ~ 15μmol/L	Dog: 0.1 ~ 0.9mg/dL; Cat: 0.1 ~ 0.9mg/dL
CRE	Dog: 27 ~ 149μmol/L; Cat:27 ~ 223μmol/L	Dog: 0.3 ~ 1.7mg/dL; Cat:0.3 ~ 2.5mg/dL
BUN	Dog: 2.5 ~ 11.5mmol/L Cat: 3.6 ~ 15.5mmol/L	Dog: 7 ~ 32mg/dL Cat: 10 ~ 43mg/dL
GLU	Dog:3.89 ~ 7.95mmol/L Cat:4.11 ~ 8.84mmol/L	Dog:70 ~ 143mg/dL Cat:74 ~ 159mg/dL
CHOL	Dog: 2.84 ~ 8.26mmol/L Cat: 1.68 ~ 5.81mmol/L	Dog: 110 ~ 320mg/dL Cat: 65 ~ 225mg/dL
K^+	Dog: 3.7 ~ 5.8mmol/L; Cat: 3.7 ~ 5.8mmol/L	Dog:3.7 ~ 5.8mmol/L; Cat: 3.7 ~ 5.8mmol/L
AMY	Dog: 200 ~ 1800U/L; Cat: 200 ~ 1800U/L	Dog: 200 ~ 1800U/L; Cat: 200 ~ 1800U/L

Ca	Dog: 1.98 ~ 2.95mmol/L; Cat: 1.95 ~ 2.95mmol/L	Dog: 7.9 ~ 11.8mg/dL; Cat: 7.8 ~ 11.8mg/dL
P	Dog: 0.81 ~ 2.2mmol/L; Cat: 1 ~ 2.74mmol/L	Dog: 2.5 ~ 6.8mg/dL; Cat: 3.1 ~ 8.5mg/dL
TBA	Dog:0~20μmol/L Cat: 0~15μmol/L	Dog: 0~20μmol/L Cat:0~15μmol/L
Na^+	Dog:138 ~ 160mmol/L; Cat: 142 ~ 164mmol/L	Dog:138 ~ 160mmol/L; Cat: 142 ~ 164mmol/L

【Interpretation of Results】

Physiological interferents, such as hemolysis, icterus, and lipemia, can cause changes in the reported concentrations of certain analytes. Sample indices are printed at the bottom of each printout to inform the operator about any abnormalities in the sample. The operator should take care to avoid hemolysis caused by improper blood collection techniques.

The CelercareV or the PointcareV chemistry analyzer suppresses any results that are affected by >10% interference from hemolysis, lipemia or icterus. “HEM”, “LIP”, or “ICT” respectively, is printed on the printout in place of the result.

For the same sample, the result of using anticoagulant whole blood and plasma is 0.2 - 0.5 mmol/L lower than those using serum.

The potassium assay is a coupled pyruvate kinase (PK) / lactate dehydrogenase (LDH) assay. Therefore, in cases of extreme muscle trauma or highly elevated levels of creatine kinase (CK), The Celercare V or the Pointcare V chemistry analyzer may report a falsely elevated potassium (K^+) value. In such cases, unexpected high potassium recoveries need to be confirmed utilizing a different methodology.

Any result for a particular test that exceeds the assay range should be analyzed by another approved test method or sent to a referral laboratory. Do not dilute the sample and run it again on the CelercareV or the PointcareV chemistry analyzer.

【Limitations of Procedure】

The Health Check Plus Profile (15+5) should be used with the CelercareV or the PointcareV chemistry analyzer, and is just used for in vitro diagnosis (IVD).

As with any diagnostic test procedure, all other test procedures including the clinical status of the patient, should be considered prior to final diagnosis.

【Performance Characteristics】

Accuracy

Analyte	The relative deviation or absolute deviation should meet the following requirements
TP	B% ≤ 5.0%
ALB	B% ≤ 6.0%
ALT	B% ≤ 15.0%
ALP	B% ≤ 10.0%
TBIL	B%≤10.0%
CRE	B% ≤ 10.0%

BUN	B%≤15.0%
GLU	B% ≤ 20.0%
CHOL	B%≤10.0%
K^+	B% ≤ 15.0%
Na	B% ≤ 15.0%
AMY	B% ≤ 10.0%
Ca	B% ≤ 5.0%
P	B% ≤ 10.0%
TBA	B%≤15.0%

Batch precision

Analyte	Coefficient of variation (≤ *)
TP	2.0%
ALB	2.0%
ALT	5.0%
ALP	5.0%
TBIL	5.0%
CRE	5.0%
BUN	5.0%
GLU	5.0%
CHOL	4.0%
K^+	5.0%
Na^+	5.0%
AMY	5.0%
Ca	3.0%
P	5.0%
TBA	5.0%

Inter batch precision

Analyte	Relative Range (≤ *)
TP	5.0%
ALB	5.0%
ALT	10.0%
ALP	10.0%
TBIL	10.0%
CRE	10.0%
BUN	10.0%
GLU	10.0%
CHOL	6.0%
K^+	10.0%
Na^+	10.0%
AMY	5.0%

Ca	10.0%
P	10.0%
TBA	10.0%

Dynamic Ranges

Analyte	Dynamic Ranges
TP	20 ~100g/L
ALB	10~60g/L
ALT	5 ~ 1500U/L
ALP	5 ~ 2000U/L
TBIL	2~800μmol/L
CRE	20 ~ 2000μmol/L
BUN	0.9 ~35.7mmol/L
GLU	1 ~ 35mmol/L
CHOL	0.5 ~14mmol/L
K^+	1 ~ 8 mmol/L
Na^+	90 ~ 170mmol/L
AMY	5~ 3500U/L
Ca	0.5 ~ 4mmol/L
P	0.2 ~ 7mmol/L
TBA	0 ~ 150μmol/L

【Notes】

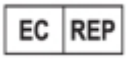
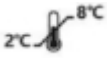
Used reagent discs contain animal body fluids. It is essential to follow good laboratory safety practices when handling and disposing of these used discs. For instructions on cleaning biohazardous spills, refer to the Celercare V or Pointcare V chemistry analyzer Operator's Manual.

The reagent discs are made of plastic and may crack or chip if dropped. Never use a disc that has been dropped, as it may spray biohazardous material throughout the interior of the analyzer.

Reagent beads may contain acids or caustic substances. Operators do not come into contact with the reagent beads when following the recommended procedures. It is important to avoid ingestion, skin contact, or inhalation of the reagent beads.

【Symbols Used in Labelling】

Symbol	Explanation
Veterinary	Veterinary use only
	Manufacturer

	Unique device identifier
	Authorized representative in the European Community
	Use-by date
	Batch code
	Date of manufacture
	Consult instructions for use
	Limit of temperature
	Do not re-use

【Manufacturer】

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Learn more about MNCHIP, other products can log in: http://www.mnchip.com

Ver1.1