



**C-Peptide, Insulin (C-Pep/Ins)  
Diabetes Panel VAST® Test System**  
**Product Code: 7375-300**

**1.0 INTRODUCTION**

**Intended Use: The Quantitative Determination of Insulin or C-Peptide levels in human serum by a Microplate Enzyme Immunoassay, Chemiluminescence.**

**2.0 SUMMARY AND EXPLANATION OF THE TEST**

Diabetes is one of the leading causes of disability and death in the U.S. It affects an estimated 16 million Americans, about one-third of whom do not even know they have the disease. The causes of diabetes are not precisely known, but both genetic and environmental factors play a significant role. The disease is marked by deficiencies in the body's ability to produce and properly use insulin. The most common forms of diabetes are type 1, in which the body's ability to produce insulin is destroyed, and type 2, in which the body is resistant to insulin even though some amount of insulin may be produced.

In-vitro determination of insulin and C-Peptide levels help in the differential diagnosis of liver disease, acromegaly, Cushing's syndrome, familial glucose intolerance, insulinoma, renal failure, ingestion of accidental oral hypoglycemic drugs or insulin induced factitious hypoglycemia. Both insulin and C-Peptide are produced by enzymatic cleavage of proinsulin. Proinsulin is stored in the secretory granules of pancreatic β-cells and is split into a 31 amino acid connecting peptide (C-Peptide; MW 3600) and insulin (MW 6000). C-Peptide is devoid of any biological activity, but appears necessary to maintain the structural integrity of insulin. Although insulin and C-Peptide are secreted into portal circulation in equimolar concentrations, fasting levels of C-Peptide are 5-10 fold higher than those of insulin owing to the longer half-life of C-Peptide. The liver does not extract C-Peptide, however; it is removed from the circulation by degradation in the kidneys with a fraction passing out unchanged in urine. Urine C-Peptide levels thus correlate well with fasting C-Peptide levels in serum. The glucagon stimulated C-Peptide determination is often used for differential diagnosis of insulin-dependent from non-insulin-dependent diabetic patients.

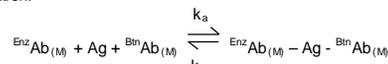
On the other hand, the circulatory insulin can be found at much higher levels in patients with pancreatic tumors. These tumors secrete abnormally high levels of insulin and thus cause hypoglycemia. Accordingly, fasting hypoglycemia associated with inappropriately high concentrations of insulin strongly suggests an islet-cell tumor (insulinoma). To distinguish insulinomas from factitious hypoglycemia due to insulin administration, serum C-peptide values are recommended. These insulinomas can be localized by provocative intravenous doses of tolbutamide and calcium.

**3.0 PRINCIPLE**

**Immunoenzymometric assay (TYPE 3):** The essential reagents required for an immunoenzymometric assay include high affinity and specificity antibodies (Ab), (enzyme conjugated and immobilized), with different and distinct epitope recognition, **in excess**, and native antigen (Ag). In this procedure, the

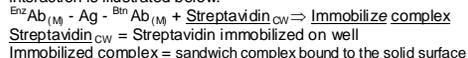
immobilization takes place during the assay at the surface of a microplate well through the interaction of streptavidin coated on the well and exogenously added biotinylated monoclonal Insulin antibody.

Upon mixing monoclonal biotinylated antibody, the enzyme-labeled antibody and a serum containing the native antigen, reaction results between the native antigen and the antibodies, without competition or steric hindrance, to form a soluble sandwich complex. The interaction is illustrated by the following equation:



$\text{Bn}^{\text{Ab}}_{(\text{M})}$  = Biotinylated Monoclonal Ab (Excess Quantity)  
 $\text{Ag}$  = Native Antigen (Variable Quantity)  
 $\text{Enz}^{\text{Ab}}_{(\text{M})}$  = Enzyme labeled Monoclonal Ab (Excess Quantity)  
 $\text{Enz}^{\text{Ab}}_{(\text{M})} - \text{Ag} - \text{Bn}^{\text{Ab}}_{(\text{M})}$  = Antigen-Antibodies complex  
 $k_a$  = Rate Constant of Association  
 $k_{-a}$  = Rate Constant of Dissociation

Simultaneously, the complex is deposited to the well through the high affinity reaction of streptavidin and biotinylated antibody. This interaction is illustrated below:



After equilibrium is attained, the antibody-bound fraction is separated from unbound antigen by decantation or aspiration. The enzyme activity in the antibody-bound fraction is directly proportional to the native antigen concentration. By utilizing several different serum references of known antigen values, a dose response curve can be generated from which the antigen concentration of an unknown can be ascertained.

**4.0 REAGENTS**

**Materials Provided:**

**A. C-Pep/Ins Calibrators – 2ml/vial (Dried) – Icons A – F**  
 Six (6) vials of references for Insulin and C-Peptide antigens at levels of 0(A), 5(B), 25(C), 50(D), 100(E), and 300(F)  $\mu\text{U/ml}$  for Insulin and 0(A), 0.2(B), 1.0(C), 2.0(D), 5.0(E), and 10.0(F)  $\text{ng/ml}$  for C-Peptide. **For C-Peptide, the assay should be performed immediately;** reconstituted vials can be stored at 2-8°C for 8 hours then discarded. For Insulin, the reconstituted calibrators are stable for 3 days when stored at 2-8°C. In order to store for a longer period of time aliquot the reconstituted calibrators in cryo vials and store at -20°C. **DO NOT FREEZE THAW MORE THAN ONCE.** A preservative has been added  
**Note:** The human serum based calibrators were calibrated using a reference preparation assayed against the WHO 1st IRP 66/304 for insulin and WHO 1st IRP 84/510 for C-Peptide.

**B. Insulin Tracer Reagent – 13ml/vial - Icon  $\text{\textcircled{E}}$**   
 One (1) vial containing enzyme labeled affinity purified monoclonal mouse x-insulin IgG, biotinylated monoclonal mouse x-insulin IgG in buffer, dye, and preservative. Store at 2-8°C.

**C. C-Peptide Tracer Reagent – 13ml/vial - Icon  $\text{\textcircled{E}}$**   
 One (1) vial containing enzyme labeled affinity purified monoclonal mouse antibody, biotinylated monoclonal mouse IgG in buffer, dye, and preservative. Store at 2-8°C.

**D. Light Reaction Wells – 96 wells – Icon  $\downarrow$**   
 One 96-well white microplate coated with streptavidin and packaged in an aluminum bag with a drying agent. Store at 2-8°C.

**E. Wash Solution Concentrate – 20 ml - Icon  $\blacklozenge$**   
 One (1) vial containing a surfactant in phosphate buffered saline. A preservative has been added. Store at 2-8°C.

**F. Signal Reagent A – 7ml/vial – Icon C<sup>A</sup>**  
 One (1) vial containing luminol in buffer. Store at 2-8°C

**G. Signal Reagent B – 7ml/vial – Icon C<sup>B</sup>**  
 One (1) vial containing hydrogen peroxide ( $\text{H}_2\text{O}_2$ ) in buffer. Store at 2-8°C

**H. Product Instructions**

**Note 1:** Do not use reagents beyond the kit expiration date.  
**Note 2:** Avoid extended exposure to heat and light. **Opened reagents are stable for sixty (60) days when stored at 2-8°C except for calibrators. Kit and component stability**

**are identified on the label.**

**Note 3:** Above reagents are for a single 96-well microplate.

**4.1 Required But Not Provided:**

1. Pipette(s) capable of delivering 0.050 & 0.100ml (50 & 100 $\mu\text{l}$ ) volumes with a precision of better than 1.5%.
2. Dispenser(s) for repetitive deliveries of 0.100 & 0.350ml (100 & 350 $\mu\text{l}$ ) volumes with a precision of better than 1.5% (optional).
3. Microplate washer or a squeeze bottle (optional).
4. Microplate Luminometer
5. Absorbent Paper for blotting the microplate wells.
6. Plastic wrap or microplate cover for incubation steps.
7. Vacuum aspirator (optional) for wash steps.
8. Timer.
9. Storage container for storage of wash buffer.
10. Distilled or deionized water.
11. Quality Control Materials.

**5.0 PRECAUTIONS**

**For In Vitro Diagnostic Use  
Not for Internal or External Use in Humans or Animals**

All products that contain human serum have been found to be non-reactive for Hepatitis B Surface antigen, HIV 1&2 and HCV antibodies by FDA required tests. Since no known test can offer complete assurance that infectious agents are absent, all human serum products should be handled as potentially hazardous and capable of transmitting disease. Good laboratory procedures for handling blood products can be found in the Center for Disease Control / National Institute of Health, "Biosafety in Microbiological and Biomedical Laboratories," 2nd Edition, 1988, HHS

**Safe disposal of kit components must be according to local regulatory and statutory requirement.**

**6.0 SPECIMEN COLLECTION AND PREPARATION**

The specimens shall be blood, serum or plasma in type, and the usual precautions in the collection of venipuncture samples should be observed. For accurate comparison to established normal values, a fasting morning serum sample should be obtained. The blood should be collected in a plain redtop venipuncture tube without additives or anti-coagulants (for serum) or evacuated tube(s) containing EDTA or heparin. Allow the blood to clot for serum samples. Centrifuge the specimen to separate the serum or plasma from the cells.

**In patients receiving therapy with high biotin doses (i.e. >5mg/day), no sample should be taken until at least 8 hours after the last biotin administration, preferably overnight to ensure fasting sample.**

Samples may be refrigerated at 2-8°C for a maximum period of five (5) days. If the specimen(s) cannot be assayed within this time, the sample(s) may be stored at temperatures of -20°C for up to 30 days. Avoid repetitive freezing and thawing. When assayed in duplicate, 0.100ml (100 $\mu\text{l}$ ) of the specimen is required.

**7.0 QUALITY CONTROL**

Each laboratory should assay controls at levels in the low, normal and elevated range for monitoring assay performance. These controls should be treated as unknowns and values determined in every test procedure performed. Quality control charts should be maintained to follow the performance of the supplied reagents. Pertinent statistical methods should be employed to ascertain trends. Significant deviation from established performance can indicate unnoticed change in experimental conditions or degradation of kit reagents. Fresh reagents should be used to determine the reason for the variations.

**8.0 REAGENT PREPARATION**

1. **Wash Buffer**  
 Dilute contents of wash solution to 1000ml with distilled or deionized water in a suitable storage container. Store at 2-30°C for up to 60 days.
2. **Working Signal Reagent Solution – Store at 2-8°C**  
 Determine the amount of reagent needed and prepare by mixing equal portions of Signal Reagent A and Signal Reagent B in a clean container. For example, add 1 ml of A and 1ml of B per two (2) eight well strips (a slight excess of solution is

made). **Discard the unused portion if not used within 36 hours after mixing.** If complete utilization of the reagents is anticipated within the above time constraint, pour the contents of Signal Reagent B into Signal Reagent A and label accordingly.

**Note 1: Do not use reagents that are contaminated or have bacteria growth.**

**9.0 TEST PROCEDURE**

*Before proceeding with the assay, bring all reagents, reference calibrators and controls to room temperature (20 - 27 C).  
**\*\*Test procedure should be performed by a skilled individual or trained professional\*\****

1. Format the microplates' wells for calibrator, control and patient specimen to be assayed in duplicate. **Replace any unused microwell strips back into the aluminum bag, seal and store at 2-8°C.**
2. Pipette 0.050ml (50 $\mu\text{l}$ ) of the appropriate calibrators, controls and samples into the assigned wells.
3. Add 0.100ml (100 $\mu\text{l}$ ) of the Insulin or C-Peptide Tracer Reagent to each well. **It is very important to use the correct 'Tracer Reagent' for each assay for accurate results.**
4. Swirl the microplate gently for 20-30 seconds to mix. Cover with a plastic wrap.
5. Incubate for 60 minutes at room temperature (20-27°C).
6. Discard the contents of the microplate by decantation or aspiration. If decanting, tap and blot the plate dry with absorbent paper.
7. Add 0.350ml (350 $\mu\text{l}$ ) of wash buffer (see Reagent Preparation Section), decant (tap and blot) or aspirate. Repeat four (4) additional times for a total of five (5) washes. **An automatic or manual plate washer can be used. Follow the manufacturer's instruction for proper usage. If a squeeze bottle is used, fill each well to the top by squeezing the container. Avoiding air bubbles. Decant the wash and repeat four (4) additional times.**
8. Add 0.100ml (100 $\mu\text{l}$ ) of working signal reagent solution to all wells (see "Reagent Preparation"). **Always add reagents in the same order to minimize reaction time differences between wells. Do not shake the plate.  
 DO NOT SHAKE PLATE AFTER SIGNAL ADDITION**
9. Incubate at room temperature for five (5) minutes in the dark.
10. Read the 'Relative Light Units (RLUs) in each well using a 96 microplate luminometer for 0.2 – 1.0 seconds per well. **The results should be read within thirty (30) minutes of adding the signal solution.**

**10.0 CALCULATION OF RESULTS**

A dose response curve is used to ascertain the concentration of Insulin or C-Peptide in unknown specimens.

1. Record the RLUs obtained from the printout of the microplate reader as outlined in Example 1 or Example 2.
2. Plot the RLUs for each duplicate serum reference versus the corresponding Insulin or C-Peptide concentration in  $\mu\text{U/ml}$  or  $\text{ng/ml}$  on linear graph paper (do not average the duplicates of the serum references before plotting).
3. Draw the best-fit curve through the plotted points.
4. To determine the concentration of Insulin or C-Peptide for an unknown, locate the average RLUs of the duplicates for each unknown on the vertical axis of the graph, find the intersecting point on the curve, and read the concentration (in  $\mu\text{U/ml}$ ) from the horizontal axis of the graph (the duplicates of the unknown may be averaged as indicated). In the following example for the Insulin (C-Peptide) concentration, the average RLU (10217) (**12864**) intersects the dose response curve at 34.7 $\mu\text{U/ml}$  (**1.18ng/ml**) (See Examples 1-2 and Figures 1-2).

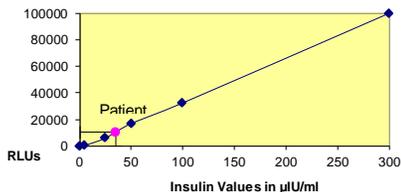
**Note:** Computer data reduction software designed for chemiluminescence assays may also be used for the data reduction. **If such software is utilized, the validation of the software should be ascertained.**

**Note 2:** The data presented in Examples 1-2 and Figures 1-2 are for illustration only and **should not** be used in lieu of a dose response curve prepared with each assay. In addition, the RLUs of the calibrators have been normalized to 100,000 RLUs for the F calibrator (greatest light output). This conversion eliminates differences caused by efficiency of the various instruments that can be used to measure light output.

**EXAMPLE 1**

Sample I.D.	Well Number	Abs (A)	Mean Abs (B)	Value (µIU/ml)
Cal A	A1	18	23	0
	B1	28		
Cal B	C1	407	401	5
	D1	394		
Cal C	E1	5983	6014	25
	F1	6044		
Cal D	G1	16955	16893	50
	H1	16832		
Cal E	A2	32659	32464	100
	B2	32269		
Cal F	C2	98734	100000	300
	D2	101266		
Ctrl 1	E2	270	282	3.9
	F2	294		
Ctrl 2	G2	41874	41974	123.7
	H2	42074		
Patient 1	A3	10290	10217	34.7
	B3	10144		

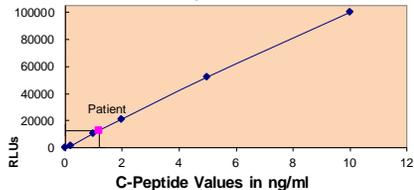
**Figure 1**



**EXAMPLE 2**

Sample I.D.	Well Number	Abs (A)	Mean Abs (B)	Value (ng/ml)
Cal A	A1	163	161	0
	B1	160		
Cal B	C1	1402	1432	0.2
	D1	1462		
Cal C	E1	10416	10837	1
	F1	11257		
Cal D	G1	20703	21370	2
	H1	22038		
Cal E	A2	54430	52387	5
	B2	50387		
Cal F	C2	100672	100000	10
	D2	99328		
Ctrl 1	E2	15212	15610	1.43
	F2	16008		
Ctrl 2	G2	61273	61198	5.84
	H2	61122		
Patient	A3	12617	12864	1.18
	B3	13110		

**Figure 1**



**11.0 QC PARAMETERS**

In order for the assay results to be considered valid the following criteria should be met:

1. The Dose Response Curve (80%; 50% & 20% intercepts) should be within established parameters.
2. Four out of six quality control pools should be within the established ranges.

**12.0 RISK ANALYSIS**

The MSDS and Risk Analysis Form for this product are available on request from Monobind, Inc.

**12.1 Assay Performance**

1. It is important that the time of reaction in each well is held constant to achieve reproducible results.
2. Pipetting of samples should not extend beyond ten (10) minutes to avoid assay drift.
3. Highly lipemic, hemolyzed or grossly contaminated specimen(s) should not be used.
4. If more than one (1) plate is used, it is recommended to repeat the dose response curve.
5. The addition of signal reagent initiates a kinetic reaction, therefore the signal reagent(s) should be added in the same sequence to eliminate any time-deviation during reaction.
6. Failure to remove adhering solution adequately in the aspiration or decantation wash step(s) may result in poor replication and spurious results.
7. Use components from the same lot. No intermixing of reagents from different batches.
8. Patient samples with Insulin concentrations above 300 µIU/ml (Insulin) or 10 ng/ml (C-Peptide) may be diluted with the zero calibrator and re-assayed. Multiply the value obtained by the dilution factor to obtain the corrected value.
9. Accurate and precise pipetting, as well as following the exact time and temperature requirements prescribed, is essential. Any deviation from Monobind IFU may yield inaccurate results.
10. All applicable national standards, regulations and laws, including good laboratory procedures, must be strictly followed to ensure compliance and proper device usage.
11. It is important to calibrate all the equipment e.g. Pipettes, Readers, Washers and the automated instruments used with this device, and to perform routine preventative maintenance.
12. Risk Analysis- as required by CE Mark IVD Directive 98/79/EC - for this and other devices, made by Monobind, can be requested via email from [Monobind@monobind.com](mailto:Monobind@monobind.com).

**12.2 Interpretation**

1. **Measurements and interpretation of results must be performed by a skilled individual or trained professional.**
2. Laboratory results alone are only one aspect for determining patient care and should not be the sole basis for therapy, particularly if the results conflict with other determinants.
3. The reagents for the test system procedure have been formulated to eliminate maximal interference; however, potential interaction between rare serum specimens and test reagents can cause erroneous results. Heterophilic antibodies often cause these interactions and have been problems for all kinds of immunoassays (Boscato LM Stuart MC. 'Heterophilic antibodies: a problem for all immunoassays' Clin Chem 1988: 3427-33). For diagnostic purposes, the results from this assay should be used in combination with clinical examination, patient history and all other clinical findings.
4. For valid test results, adequate controls and other parameters must be within the listed ranges and assay requirements.
5. If test kits are altered, such as by mixing parts of different kits, which could produce false test results, or if results are incorrectly interpreted, Monobind shall have no liability.
6. If computer controlled data reduction is used to interpret the results of the test, it is imperative that the predicted values for the calibrators fall within 10% of the assigned concentrations.

**13.0 EXPECTED VALUES**

C-Peptide values are consistently higher in plasma than in serum; thus, serum is preferred. Compared with fasting values in non-obese non-diabetic individuals, C-Peptide levels are higher in obese non-diabetic subjects and lower in trained athletes.

Based on the clinical data gathered by Monobind in concordance with the published literature the following ranges have been assigned. **These ranges should be used as guidelines only.**

Adult (Normal)	0.7 – 1.9 ng/ml
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Insulin values are consistently higher in plasma than in serum; thus, serum is preferred. Compared with fasting values in non-obese non-diabetic individuals, insulin levels are higher in obese non-diabetic subjects and lower in trained athletes. Although proinsulin cross reacts with most competitive insulin assays, there is less than 1% cross reaction found with proinsulin using the Insulin test system.

Based on the clinical data gathered by Monobind in concordance with the published literature the following ranges have been assigned. **These ranges should be used as guidelines only.**

Children < 12 yrs	< 10 µIU/ml
Adult (Normal)	0.7 – 9.0 µIU/ml
Diabetic (Type II)	0.7 – 25 µIU/ml

It is important to keep in mind that establishment of a range of values, which can be expected to be found by a given method for a population of "normal" persons, is dependent upon a multiplicity of factors: the specificity of the method, the population tested and the precision of the method in the hands of the analyst. For these reasons, each laboratory should depend upon the range of expected values established by the Manufacturer only until an in-house range can be determined by the analysts using the method with a population indigenous to the area in which the laboratory is located.

**14.0 PERFORMANCE CHARACTERISTICS**

**14.1 Precision**

The within and between assay precision of the C-Pep/Ins VAST® AccuLite® CLIA Test System were determined by analyses on three different levels of pool control sera. The number, mean value, standard deviation and coefficient of variation for each of these control sera are presented in Table 1 and Table 2.

**TABLE 1**  
Insulin (µIU/ml) or C-Peptide (ng/ml) within assay precision

Sample	N	X	σ	C.V.
Pool 1	24 (20)	7.86 (1.49)	0.602 (0.12)	7.6% (7.7%)
Pool 2	24 (20)	45.23 (5.97)	4.26 (0.35)	9.4% (5.8%)
Pool 3	24 (20)	133.92 (12.00)	5.69 (0.15)	4.2% (1.3%)

**TABLE 2**  
Insulin (µIU/ml) or C-Peptide (ng/ml) between assay precision

Sample	N	X	σ	C.V.
Pool 1	16 (20)	10.16 (1.30)	0.98 (0.11)	9.6% (8.7%)
Pool 2	16 (20)	45.53 (6.10)	3.48 (0.60)	7.7% (9.8%)
Pool 3	16 (20)	140.53 (13.16)	7.27 (1.25)	5.2% (9.5%)

\*As measured in duplicate over ten days.

**14.2 Sensitivity**

The sensitivity (detection limit) was ascertained by determining the variability of the 0 µIU/ml or ng/ml serum calibrator and using the 2σ (95% certainty) statistic to calculate the minimum dose. The assay sensitivity was found to be 0.114 µIU/ml for Insulin and 0.012 ng/ml for C-Peptide.

**14.3 Accuracy**

The C-Pep/Ins VAST® AccuLite® CLIA Test System assay was compared with a reference method. Biological specimens from population (symptomatic and asymptomatic) were used (the values ranged from 0.01 µIU/ml - 132 µIU/ml). The total number of specimens was 105. The data obtained is displayed in Table 3.

**TABLE 3 - Insulin**

Method	Mean (x)	Least Square Regression Analysis	Correlation Coefficient
This Method	10.8	y = -0.8 + 0.91(x)	0.985
Reference	11.2		

The C-Pep/Ins VAST® AccuLite® CLIA Test System was compared with a reference microplate enzyme immunoassay (ELISA). Biological specimens from population (symptomatic and asymptomatic) were used. (The values ranged from 0.2 ng/ml - 11.8 ng/ml). The total number of such specimens was 133. The data obtained is displayed in Table 4 (see next column).

**TABLE 4 - C-Peptide**

Method	Mean (x)	Least Square Regression Analysis	Correlation Coefficient
This Method (y)	1.068	y = 0.21 + 0.804(x)	0.962
Reference (x)	1.066		

Only slight amounts of bias between the Ins/C-Pep VAST® AccuLite® CLIA Test System and the reference methods are indicated by the closeness of the mean values. The least square regression equation and correlation coefficient indicates excellent method agreement.

**14.4 Specificity**

The cross-reactivity of the Ins/C-Pep VAST® AccuLite® CLIA Test System to selected substances was evaluated by adding the interfering substance(s) to a serum matrix at the following concentration(s). The cross-reactivity was calculated by deriving a

ratio between dose of interfering substance to dose of insulin or C-Peptide needed to produce the same absorbance.

**Insulin**

Substance	Cross Reactivity	Concentration
Insulin	1.0000	-
Proinsulin	0.0078	100 ng/ml
C-Peptide	non-detectable	75 ng/ml
Glucagon	non-detectable	150 ng/ml

**C-Peptide**

Substance	Cross Reactivity	Concentration
C-Peptide	1.000	-
Proinsulin	0.120	100 ng/ml
Insulin	non-detectable	1.0 µIU/ml
Glucagon	non-detectable	150 ng/ml

**15.0 REFERENCES**

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2. Gerbitz VKD, "Pancreatische B-zellen Peptide: Kinetic and Konzentration von Proinsulin, Insulin und C-peptide in Plasma and Urine Probleme der Meszmethoden Klinische und Literaturubersicht", *J Clin Chem Biochem*, 18, 313-326 (1980).
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Glossary of Symbols  
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